POC 2021 DATA ACQUISITION MANUAL

PROSTATE CANCER

OVARIAN CANCER

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SECTION I - INTRODUCTION/DATA MANAGEMENT

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1. STUDY OVERVIEW

1.1. The Patterns of Care Study funded in fiscal year 2024 will examine the diagnosis, demographic and tumor characteristics, biomarkers, and therapies offered to patients diagnosed in 2021 with prostate cancer (AJCC stage I - IV) and ovarian cancer (AJCC stage I - IV), including primary cancers of the fallopian tubes and peritoneum. The study will also collect data on documentation of the effects of the COVID-19 pandemic on screening, diagnosis, treatment, and palliative care for these cancers from the medical record. The National Cancer Institute has a Congressional Mandate to report on the dissemination of state-of-the-art therapy into community practice.

1.2. PROSTATE CANCER

Estimated new cases and deaths from prostate cancer in the United States in 2023 are:

- New cases: 288,300
- Deaths: 34,700

The median age at diagnosis of prostate cancer is 67 years. Prostate cancer may be cured when localized, and it frequently responds to treatment when widespread. The rate of tumor growth varies from very slow to moderately rapid, and some patients may have prolonged survival even after the cancer has metastasized to distant sites, such as bone. The 5-year relative survival rate for men diagnosed in the United States from 2012 to 2018 with local or regional disease was greater than 99%, and the rate for distant disease was 32%; a 97% survival rate was observed for all stages combined. The approach to treatment is influenced by age and coexisting medical problems. Side effects of various forms of treatment should be considered in selecting appropriate management.

Many patients—especially those with localized tumors—may die of other illnesses without ever having suffered disability from prostate cancer, even if managed conservatively without an attempt at curative therapy. In part, these favorable outcomes are likely the result of widespread screening with the prostate-specific antigen (PSA) test, which can identify patients with asymptomatic tumors that have little or no lethal potential. There is a large number of these clinically indolent tumors, estimated to range from 30% to 70% of men older than 60 years, based on autopsy series of men dying of causes unrelated to prostate cancer.

Because diagnostic methods have changed over time, any analysis of survival after treatment of prostate cancer and comparison of the various treatment strategies is complicated by evidence of increasing diagnosis of nonlethal tumors. Nonrandomized comparisons of treatments may be confounded not only by patient selection factors but also by time trends. Another issue complicating comparisons of outcomes among nonconcurrent series of patients is the possibility of changes in criteria for the histological diagnosis of prostate cancer. This phenomenon creates a statistical

artifact that can produce a false sense of therapeutic accomplishment and may also lead to more aggressive therapy. Controversy exists about the value of screening, the most appropriate staging evaluation, and the optimal treatment of each stage of the disease.

Pathology

More than 95% of primary prostate cancers are adenocarcinomas. Prostate adenocarcinomas are frequently multifocal and heterogeneous in patterns of differentiation. Prostatic intraepithelial neoplasia (PIN) (noninvasive atypical epithelial cells within benign-appearing acini) is often present in association with prostatic adenocarcinoma. PIN is subdivided into low grade and high grade. The high-grade form may be a precursor of adenocarcinoma.

Gleason score

The histological grade of prostate adenocarcinomas is usually reported according to one of the variations of the Gleason scoring system, which provides a useful, albeit crude, adjunct to tumor staging in determining prognosis. The Gleason score is calculated based on the dominant histological grades, from grade 1 (well differentiated) to grade 5 (very poorly differentiated). The classical score is derived by adding the two most prevalent pattern grades, yielding a score ranging from 2 to 10. Because there is some evidence that the least-differentiated component of the specimen may provide independent prognostic information, the score is often provided by its separate components (e.g., Gleason score 3 + 4 = 7; or 4 + 3 = 7).

There is evidence that, over time, pathologists have tended to award higher Gleason scores to the same histological patterns, a phenomenon sometimes termed grade inflation. This phenomenon complicates comparisons of outcomes in current versus historical patient series. As a result, Gleason-score standardized prostate cancer mortality rates for these men were artifactually improved from 2.08 to 1.50 deaths per 100-person years—a 28% decrease even though overall outcomes were unchanged.

Staging Information for Prostate Cancer

In 1997, the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer adopted a revised TNM (tumor, node, metastasis) system, which used the same broad T-stage categories as the Jewett system but included subcategories of T stage, such as a stage to describe patients diagnosed through PSA screening. This revised TNM system more precisely stratifies newly diagnosed patients. Staging information for prostate cancer is available at https://www.cancer.gov/types/prostate/hp/prostate-treatment-pdq#_58.

Treatment

Local treatment modalities are associated with prolonged disease-free survival (DFS) for many patients with localized prostate cancer but are rarely curative in patients with locally extensive tumors. Because of clinical understaging using current diagnostic techniques, even when the cancer appears clinically localized to the prostate gland, some patients develop disseminated tumors after local therapy with surgery or radiation.

Treatment options for each stage of prostate cancer are presented in Table 1.

Table 1: Treatment Options for Prostate Cancer by Stage

Stage	Treatment Options
Stage I Prostate Cancer	Watchful waiting or active surveillance/active monitoring
	Radical prostatectomy
	External-beam radiation therapy (EBRT)
	Interstitial implantation of radioisotopes
	Photodynamic therapy (under clinical evaluation)
	Bicalutamide (under clinical evaluation)
Stage II Prostate Cancer	Watchful waiting or active surveillance/active monitoring
	Radical prostatectomy
	EBRT with or without hormonal therapy
	Interstitial implantation of radioisotopes
	Cryosurgery (under clinical evaluation)
	Proton-beam therapy (under clinical evaluation)
	Photodynamic therapy (under clinical evaluation)
	Neoadjuvant hormonal therapy (under clinical evaluation)
	Bicalutamide (under clinical evaluation)
Stage III Prostate Cancer	EBRT with or without hormonal therapy
	Hormonal manipulations with or without radiation therapy
	Radical prostatectomy with or without EBRT
	Watchful waiting or active surveillance/active monitoring

Stage	Treatment Options
	Cryosurgery (under clinical evaluation)
	Proton-beam therapy (under clinical evaluation)
	Bicalutamide (under clinical evaluation)
Stage IV Prostate Cancer	Hormonal manipulations
	Bisphosphonates
	EBRT with or without hormonal therapy
	Palliative radiation therapy
	Palliative surgery with transurethral resection of the prostate (TURP)
	Watchful waiting or active surveillance/active monitoring
Recurrent Prostate Cancer	Hormone therapy
	Chemotherapy for hormone-resistant prostate cancer
	Immunotherapy
	Radiopharmaceutical therapy/alpha emitter radiation
	PARP inhibitors for men with prostate cancer and BRCA1, BRCA2, and/or ATM mutations
	Cryosurgery (under clinical evaluation)

Side effects of each of the treatment approaches are covered in the relevant sections below. Patient-reported adverse effects differ substantially across the options for management of clinically localized disease, with few direct comparisons, and include watchful waiting/active surveillance/active monitoring, radical prostatectomy, and radiation therapy. The differences in adverse effects can play an important role in patient choice among treatment options. Detailed comparisons of these effects have been reported in population-based cohort studies, albeit with relatively short follow-up times of 2 to 3 years.

Watchful Waiting or Active Surveillance/Active Monitoring

Asymptomatic patients of advanced age or with concomitant illness may warrant consideration of careful observation without immediate active treatment. Watch and wait, observation, expectant management, and active surveillance/active monitoring are terms indicating a strategy that does not employ immediate therapy with curative intent.

Watchful waiting and active surveillance/active monitoring are the most commonly used terms, and the literature does not always clearly distinguish them, making the interpretation of results difficult. The general concept of watchful waiting is patient follow-up with the application of palliative care as needed to alleviate symptoms of tumor progression. There is no planned attempt at curative therapy at any point in follow-up. For example, transurethral resection of the prostate (TURP) or hormonal therapy may be used to alleviate tumor-related urethral obstruction should there be local tumor growth; hormonal therapy or bone radiation might be used to alleviate pain from metastases. Radical prostatectomy has been compared with watchful waiting or active surveillance/active monitoring in men with early-stage disease (i.e., clinical stages T1b, T1c, or T2). For more information, see the Radical Prostatectomy section.

In contrast, the strategy behind active surveillance/active monitoring is to defer therapy for clinically localized disease but regularly follow the patient and initiate local therapy with curative intent if there are any signs of local tumor progression. The intention is to avoid the morbidity of therapy in men who have indolent or nonprogressive disease but preserve the ability to cure them should the tumor progress. Active surveillance/active monitoring often involves the following:

- Regular patient visits.
- Digital rectal examinations.
- Prostate-specific antigen (PSA) testing.
- Transrectal ultrasound (in some series).
- Transrectal needle biopsies (in some series).

Patient selection, testing intervals, and specific tests, as well as criteria for intervention, are arbitrary and not established in controlled trials.

In the United States, as in other settings with widespread PSA screening, the results of conservative management of localized prostate cancer are particularly favorable. In the aggregate, men managed by watchful waiting or active surveillance/active monitoring (using various criteria, depending upon the study) have had very favorable prostate–cancer-specific mortalities ranging from about 1% to 10% (with the most favorable rates in more recent series). Most men with screen-detected prostate cancer may, therefore, be candidates for active surveillance/active monitoring, with definitive therapy reserved for signs of tumor progression.

Radical Prostatectomy

A radical prostatectomy is usually reserved for patients who:

- Are in good health and elect surgical intervention.
- Have tumor confined to the prostate gland (stage I and stage II).

Open prostatectomy can be performed by the perineal or retropubic approach. The perineal approach requires a separate incision for lymph node dissection. Laparoscopic lymphadenectomy is technically possible. Robot-assisted prostatectomy is an alternative to open prostatectomy and has become the most common technique in developed countries. In experienced hands, functional outcomes between open and robot-assisted prostatectomy appear very similar, at least in the short- to mid-term. In a randomized trial of 308 men suitable for prostatectomy, urinary, sexual, and bowel functional outcomes were similar between open retropubic and robotic surgeries at a median follow-up of 24 months. The sample size and duration of follow-up were too small to detect meaningful differences in cancer outcomes.
For small, well-differentiated nodules, the incidence of positive pelvic nodes is less than 20%, and pelvic node dissection may be omitted. With larger, less-differentiated tumors, a pelvic lymph node dissection is more important. In these cases, the value of open surgical or laparoscopic pelvic node dissection is not therapeutic, but it spares patients with positive nodes the morbidity of prostatectomy. Radical prostatectomy is usually not performed if a frozen-section evaluation of pelvic nodes reveals metastases; these patients should be considered for entry into existing clinical trials or receive radiation therapy to control local symptoms. The role of preoperative (neoadjuvant) hormonal therapy is not established.

After radical prostatectomy, pathological evaluation stratifies tumor extent into the following classes:

- Margin-positive disease—The incidence of disease recurrence increases when the tumor margins are positive. Results of the outcome of patients with positive surgical margins have not been systematically reported.
- Specimen-confined disease—The incidence of disease recurrence increases when the tumor is not specimen-confined (extracapsular).
- Organ-confined disease—Patients with extraprostatic disease (not organ-confined) are suitable candidates for clinical trials of which the Radiation Therapy Oncology Group's (RTOG) RTOG-9601 trial (NCT00002874), was an example. These trials have included evaluation of postoperative radiation delivery, cytotoxic agents, and hormonal treatment using luteinizing hormone-releasing hormone (LH-RH) agonists and/or antiandrogens.

Complications of radical prostatectomy

Complications of radical prostatectomy include the following:

- Morbidity and mortality associated with general anesthesia and a major surgical procedure.
- Urinary incontinence and impotence.
- Penile shortening.
- Inguinal hernia.
- Fecal incontinence.

Functional outcomes of radical prostatectomy with respect to sexual, urinary, bowel function, and health-related quality of life (QOL), appear to be similar whether the procedure is open retropubic, laparoscopic, or robot-assisted radical prostatectomy.

Radiation Therapy and Radiopharmaceutical Therapy

External-beam radiation therapy (EBRT)

Candidates for definitive radiation therapy must have a confirmed pathological diagnosis of cancer that is clinically confined to the prostate and/or surrounding tissues (stage I, stage II, and stage III). Staging laparotomy and lymph node dissection are not required.

Radiation therapy may be a good option for patients who are considered poor medical candidates for radical prostatectomy. These patients can be treated with an acceptably low complication rate if care is given to the delivery technique. Long-term results with radiation therapy are dependent on stage and are associated with dosimetry of the radiation.

Conventional versus hypofractionated EBRT

The more convenient schedules of hypofractionated radiation therapy (using fewer fractions at higher doses per fraction) appear to yield similar outcomes to conventional schedules of radiation, at least with respect to the intermediate outcomes of DFS and failure-free survival (low levels of evidence not known to translate into health outcomes), and early data on OS rates. However, hypofractionated radiation may incur more toxicity than standard doses, depending on the schedules used.[71]

Brachytherapy

Patients undergoing brachytherapy are often selected for favorable characteristics that include the following:
Low Gleason score.
Low PSA level.
Stage T1 to T2 tumors.

More information and further study are required to better define the effects of modern interstitial brachytherapy on disease control and QOL and to determine the contribution of favorable patient selection to outcomes

Radiopharmaceutical therapy

Alpha emitter radiation

Radium Ra 223 (223Ra) emits alpha particles (i.e., two protons and two neutrons bound together, identical to a helium nucleus) with a half-life of 11.4 days. It is administered intravenously and selectively taken up by newly formed bone stroma. The high-energy alpha particles have a short range of less than 100 mcM. 223Ra improved OS in patients with prostate cancer metastatic to bone. In a double-blind, randomized, controlled trial, 921 men with symptomatic castration-resistant prostate cancer, two or more metastases, and no known visceral metastases were randomly assigned in a 2:1 ratio to 223Ra versus placebo. 223Ra statistically significantly improved OS (median 14.9 months vs. 11.3 months), rate of symptomatic skeletal events (33% vs. 38%), and spinal cord compression (4% vs. 7%). With administration at a dose of 50kBq per kg body weight every 4 weeks for six injections, the side effects were similar to those of a placebo.

Complications of radiation therapy

Definitive EBRT can result in acute cystitis, proctitis, and enteritis. These conditions are generally reversible but may be chronic and rarely require surgical intervention. A cross-sectional survey of patients with prostate cancer who had been treated in a managed care setting by radical prostatectomy, radiation therapy, or watchful waiting and active surveillance showed substantial sexual and urinary dysfunction in the radiation therapy group.

Radiation is also carcinogenic. EBRT for prostate cancer is associated with an increased risk of bladder and gastrointestinal cancer. Brachytherapy is associated with an increased risk of bladder cancer.

Reducing complications

Potency, in most cases, is preserved with radiation therapy in the short term but appears to diminish over time. Sildenafil citrate may be effective in the management of sexual dysfunction after radiation therapy in some men.

Comparison of complications from radiation therapy and from radical prostatectomy

In general, radical prostatectomy is associated with a higher rate of urinary incontinence and early sexual impotence but a lower rate of stool incontinence and rectal injury. However, over time, the differences in sexual impotence diminish because the risk rises with time since radiation. Many side effects of definitive local therapy for prostate cancer persist well beyond a decade after therapy, and urinary problems in addition to sexual impotence may worsen with age.

Hormonal Therapy and Its Complications

Several different hormonal approaches are used in the management of various stages of prostate cancer.
These approaches include the following:

- Abiraterone acetate (added to androgen deprivation therapy [ADT])
- Bilateral orchiectomy
- Estrogen therapy
- Luteinizing hormone-releasing hormone (LH-RH) agonist therapy
- Antiandrogen therapy
- ADT
- Antiadrenal therapy
- Ketoconazole
- Aminoglutethimide

Abiraterone acetate

Abiraterone acetate has been shown to improve OS when added to ADT in men with advanced prostate cancer who have castration-sensitive disease. Abiraterone acetate is generally well-tolerated; however, it is associated with an increase in the mineralocorticoid effects of grade 3 or 4 hypertension and hypokalemia compared with ADT alone. It may also be associated with a small increase in respiratory disorders.

Bilateral orchiectomy

Benefits of bilateral orchiectomy include the following:

- Ease of the procedure
- Compliance
- Immediacy in lowering testosterone levels
- Low cost relative to the other forms of ADT

Disadvantages of bilateral orchiectomy include the following:

- Psychological effects
- Loss of libido
- Less reversible impotence
- Hot flashes
- Osteoporosis

Bilateral orchiectomy has also been associated with an elevated risk of coronary heart disease and myocardial infarction.

Estrogen therapy

Estrogens at a dose of 3 mg qd of diethylstilbestrol (DES) will achieve castrate levels of testosterone. Like orchiectomy, estrogens may cause loss of libido and impotence.

Estrogens also cause gynecomastia, and prophylactic low-dose radiation therapy to the breasts is given to prevent this complication.

DES is no longer manufactured or marketed in the United States and is seldom used today because of the risk of serious side effects, including myocardial infarction, cerebrovascular accidents, and pulmonary embolism.

Luteinizing hormone-releasing hormone (LH-RH) agonist therapy

LH-RH agonists, such as leuprolide, goserelin, and buserelin, lower testosterone to castrate levels. Like orchiectomy and estrogens, LH-RH agonists cause impotence, hot flashes, and loss of libido. Tumor flare reactions may occur transiently but can be prevented by antiandrogens or short-term estrogens at a low dose for several weeks. There is some evidence that LH-RH agonists are associated with increased risk of cardiovascular morbidity or mortality, although the results are conflicting.

Antiandrogen therapy

Antiandrogen agents used in the treatment of prostate cancer include flutamide and bicalutamide. A systematic evidence review compared nonsteroidal antiandrogen monotherapy with surgical or medical castration from 11 randomized trials in 3,060 men with locally advanced, metastatic, or recurrent disease after local therapy. Use of nonsteroidal antiandrogens as monotherapy decreased OS and increased the rate of clinical progression and treatment failure. The pure antiandrogen, flutamide, may cause diarrhea, breast tenderness, and nausea. Case reports show fatal and nonfatal liver toxic effects. Bicalutamide may cause nausea, breast tenderness, hot flashes, loss of libido, and impotence. The steroidal antiandrogen, megestrol acetate, suppresses androgen production incompletely and is generally not used as initial therapy. Additional studies that evaluate the effects of various hormone therapies on QOL are required.

ADT

A national Medicare survey of men who had undergone radical prostatectomy for prostate cancer and either had or had not undergone androgen depletion (either medically or surgically induced) showed a decrease with androgen depletion in all seven health-related QOL measures, including the following:

- Impact of cancer and treatment
- Concern regarding body image
- Mental health
- General health
- Activity
- Worries about cancer and dying
- Energy

ADT can cause osteoporosis and bone fractures. The use of ADT may be associated with complaints of penile shortening, although the data are very limited. The use of ADT has also been associated with an increased risk of colorectal cancer.

Antiadrenal therapy

Antiadrenal agents used in the treatment of prostate cancer include ketoconazole and aminoglutethimide. Long-term use of ketoconazole can result in impotence, pruritus, nail changes, and adrenal insufficiency. Aminoglutethimide commonly causes sedation and skin rashes.

Cryosurgery

Cryosurgery, or cryotherapy, is under evaluation for the treatment of localized prostate cancer. It is a surgical technique that involves destruction of prostate cancer cells by intermittent freezing of the prostate with cryoprobes, followed by thawing. There is limited evidence regarding its efficacy and safety compared with standard prostatectomy and radiation therapy, and the technique is evolving in an attempt to reduce local toxicity and normal tissue damage. The quality of evidence on efficacy is low, currently limited to case series of relatively small size, short follow-up, and surrogate outcomes of efficacy.

Serious toxic effects associated with cryosurgery include bladder outlet injury, urinary incontinence, sexual impotence, and rectal injury. Impotence is common, ranging from about 47% to 100%.
The frequency of other side effects and the probability of cancer control at 5 years' follow-up have varied among reporting centers, and series are small compared with surgery and radiation therapy. Other major complications include urethral sloughing, urinary fistula or stricture, and bladder neck obstruction.

Proton-Beam Therapy

There is interest in the use of proton-beam therapy for the treatment of prostate cancer. Although the dose distribution of this form of charged-particle radiation could theoretically improve the therapeutic ratio of prostate radiation, allowing for an increase in dose to the tumor without a substantial increase in side effects, no randomized controlled trials have been reported that compare its efficacy and toxicity with those of other forms of radiation therapy.

Photodynamic Therapy

Vascular-targeted photodynamic therapy using a photosensitizing agent has been tested in men with low-risk prostate cancer.

Neoadjuvant Hormonal Therapy

The role of neoadjuvant hormonal therapy is not established.

Bicalutamide

Bicalutamide has not been shown to improve OS in patients with localized or locally advanced prostate cancer.

1.3. OVARIAN CANCER

Estimated new cases and deaths from ovarian cancer in the United States in 2023:

- New cases: 19,710.
- Deaths:: 13,270.

Cellular Classification of Ovarian Epithelial Cancer

Table 2 describes the histological classification of ovarian epithelial cancer.

Table 2. Ovarian Epithelial Cancer Histological Classification

Histological Classification	Histological Subtypes
Serous cystomas	Serous benign cystadenomas.
	Serous cystadenomas with proliferating activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth.
	Serous cystadenocarcinomas.
Mucinous cystomas	Mucinous benign cystadenomas.

Histological Classification	Histological Subtypes
	Mucinous cystadenomas with proliferating activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth (low malignant potential or borderline malignancy).
	Mucinous cystadenocarcinomas.
Endometrioid tumors (similar to adenocarcinomas in the endometrium)	Endometrioid benign cysts.
	Endometrioid tumors with proliferating activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth (low malignant potential or borderline malignancy).
	Endometrioid adenocarcinomas.
Clear cell (mesonephroid) tumors	Benign clear cell tumors.
	Clear cell tumors with proliferating activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth (low malignant potential or borderline malignancy).
	Clear cell cystadenocarcinomas.
Unclassified tumors that cannot be allotted to one of the above groups	

Histological Classification	Histological Subtypes
No histology (cytology-only diagnosis)	
Other malignant tumors (malignant tumors other than those of the common epithelial types are not to be included with the categories listed above)	

In the absence of extra-abdominal metastatic disease, definitive staging of ovarian cancer requires surgery. The role of surgery in patients with stage IV ovarian cancer and extra-abdominal disease is yet to be established. If disease appears to be limited to the ovaries or pelvis, it is essential at laparotomy to obtain peritoneal washings and to examine and biopsy or obtain cytological brushings of the following:

- Diaphragm.
- Both paracolic gutters.
- Pelvic peritoneum.
- Para-aortic and pelvic nodes.
- Infracolic omentum.

The Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) Staging

The FIGO and the American Joint Committee on Cancer (AJCC) have designated staging to define ovarian epithelial cancer. The FIGO-approved staging system for ovarian epithelial cancer, fallopian tube cancer (FTC), and primary peritoneal cancer (PPC) is the one most commonly used.

Treatment Option Overview

Treatment options for patients with all stages of ovarian epithelial cancer, fallopian tube cancer (FTC), and primary peritoneal cancer (PPC) have consisted of surgery followed by platinum-based chemotherapy.

Early stage refers to stages I and II. However, because of high recurrence rates for stage II patients in early-stage disease trials, patients with stage II cancers have been included with patients who have more advanced-stage cancer in Gynecologic Oncology Group clinical trials since 2009. Going forward, stage I will remain a separate category for treatment considerations, but high-grade serous stage II cancers are likely to be included with more advanced stages.

The treatment options for ovarian epithelial cancer are presented in Table 3.

Table 3. Treatment Options for Ovarian Epithelial Cancer

Stage	Treatment Options
OS = overall survival; PARP = poly (ADP-ribose) polymerase.	
Early stage	Surgery with or without chemotherapy
Advanced stage	Surgery followed by platinum-based chemotherapy
	Surgery before or after platinum-based chemotherapy and/or additional consolidation therapy
	Surgery before or after platinum-based chemotherapy and the addition of bevacizumab to induction therapy and/or consolidation therapy
	Surgery before or after platinum-based chemotherapy and the addition of PARP inhibitors to induction therapy and/or consolidation therapy

Stage	Treatment Options
	Chemotherapy for patients who cannot have surgery (although the impact on OS has not been proven)
Recurrent	Platinum-containing chemotherapy regimens
	Bevacizumab, other targeted drugs, and PARP inhibitors with or without chemotherapy
	Chemotherapy
	Chemotherapy and/or bevacizumab
	Immune checkpoint inhibitors

Treatment of Early-Stage Ovarian Epithelial Cancer

Early stage refers to stage I and stage II. However, because of high recurrence rates for stage II patients in early-stage disease trials, patients with stage II cancers have been included with patients who have more advanced-stage cancer in Gynecologic Oncology Group (GOG) clinical trials since 2009. Going forward, stage I will remain a separate category for treatment considerations, but high-grade serous stage II cancers are likely to be included with more advanced stages.

Treatment Options for Early-Stage Ovarian Epithelial Cancer

Treatment options for early-stage ovarian epithelial include the following:

Surgery with or without chemotherapy

If the tumor is well differentiated or moderately well differentiated, surgery alone may be adequate treatment for patients with stage IA or IB disease. Surgery includes hysterectomy, bilateral salpingo-oophorectomy, and omentectomy. The undersurface of the diaphragm is

visualized and biopsied. Biopsies of the pelvic and abdominal peritoneum and the pelvic and para-aortic lymph nodes are also performed. Peritoneal washings are routinely obtained. In patients who desire childbearing and have grade 1 tumors, unilateral salpingo-oophorectomy may be associated with a low risk of recurrence.

In the United States, except for the most favorable subset of patients (those with stage IA well-differentiated disease), evidence based on double-blinded, randomized, controlled trials with total mortality end points supports adjuvant treatment with cisplatin, carboplatin, and paclitaxel.

The following treatments have been largely displaced by the adoption of carboplatin plus paclitaxel for early stages of high-grade ovarian cancers:

- Intraperitoneal phosphorus P 32 or radiation therapy.
- Platinum-based systemic chemotherapy alone or in combination with alkylating agents.

Treatment of Advanced-Stage Ovarian Epithelial Cancer

Treatment options for patients with all stages of ovarian epithelial cancer have consisted of surgery followed by platinum-based chemotherapy. Because of high recurrence rates for stage II patients in early-stage disease trials, patients with stage II cancers have been included with patients who have more advanced-stage cancer in Gynecologic Oncology Group (GOG) clinical trials since 2009. Going forward, stage I will remain a separate category for treatment considerations, but high-grade serous stage II cancers are likely to be included with more advanced stages. The most common approach to advanced ovarian cancer is surgery followed by adjuvant platinum-based chemotherapy.

Treatment Options for Advanced-Stage Ovarian Epithelial Cancer

Treatment options for advanced-stage ovarian epithelial cancer, FTC, and PPC include the following:

1. Surgery followed by platinum-based chemotherapy.
2. Surgery before or after platinum-based chemotherapy and/or additional consolidation therapy.
3. Surgery before or after platinum-based chemotherapy and the addition of bevacizumab to induction therapy and/or consolidation therapy.
4. Surgery before or after platinum-based chemotherapy and the addition of PARP inhibitors to induction therapy and/or consolidation therapy.
5. Chemotherapy for patients who cannot have surgery (although the impact on OS has not been proven).
   Platinum-based chemotherapy is the initial treatment for all patients diagnosed with advanced disease who undergo surgical resection and are staged with cancer that has

spread to the pelvic peritoneum (stage II) and beyond (stages III and IV). The role of surgery for patients with stage IV disease is unclear, but in most instances, the bulk of the disease is intra-abdominal, and surgical procedures similar to those used in the management of patients with stage II and III disease are applied.

Surgery has historically been done by open laparotomy performed by gynecologic oncology surgeons, and has included hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and debulking of peritoneal implants (often including resection of the bowel or adjacent organs as needed) to reduce tumor to microscopic, if it can safely be performed.

Surgery followed by platinum-based chemotherapy

Platinum agents, such as cisplatin or its less-toxic second-generation analog, carboplatin, given either alone or in combination with other drugs, are the foundation of chemotherapy regimens used. Trials by various cooperative groups (conducted from 1999 to 2010) addressed issues of optimal dose intensity for both cisplatin and carboplatin, schedule, and the equivalent results obtained with either of these platinum drugs, usually in combination with cyclophosphamide.

With the introduction of the taxane paclitaxel, two trials confirmed the superiority of cisplatin combined with paclitaxel when compared with the previous standard treatment of cisplatin plus cyclophosphamide. However, two trials that compared single-agent paclitaxel with either cisplatin or carboplatin (ICON3 and GOG-132) failed to confirm such superiority in all outcome parameters (i.e., response, time-to-progression, and survival).

Based on the evidence, the initial standard treatment for patients with ovarian cancer is the combination of cisplatin or carboplatin with paclitaxel (defined as induction chemotherapy).

Surgery before or after platinum-based chemotherapy and/or additional consolidation therapy

The pharmacological basis for the delivery of anticancer drugs by the IP route was established in the late 1970s and early 1980s. When several drugs were studied, mostly in the setting of measurable residual disease at reassessment after patients had received their initial chemotherapy, cisplatin alone and in combination received the most attention. Favorable outcomes from IP cisplatin were most often seen when tumors had shown responsiveness to platinum therapy and with small-volume tumors (usually defined as tumors <1 cm).

In the 1990s, randomized trials were conducted to evaluate whether the IP route would prove superior to the IV route. IP cisplatin was the common denominator of these randomized trials.

Surgery before or after platinum-based chemotherapy and the addition of bevacizumab to induction and/or consolidation therapy

Two phase III studies compared the outcome of standard primary cytoreductive surgery with that of neoadjuvant chemotherapy followed by interval cytoreductive surgery; both studies (described below) demonstrated that PFS and OS were noninferior with the use of primary cytoreductive surgery.

Hyperthermic peritoneal chemotherapy (HIPEC) is another pharmacologically based modality to enhance the antitumor effects via direct drug delivery to peritoneal surfaces. It was initially tested against mucinous tumors of gastrointestinal origin. Increasingly, HIPEC is being applied to ovarian cancers, with considerable variation in patient selection, drugs administered, and time at target temperatures (most often 30 minutes at 42°C). The role of HIPEC remains experimental in the treatment of patients with high-grade serous ovarian cancers.

Surgery before or after platinum-based chemotherapy and the addition of poly (ADP-ribose) polymerase (PARP) inhibitors to induction and/or consolidation therapy

PARP is a family of enzymes involved in base-excision repair of DNA single-strand breaks. In patients with homologous recombination deficiency, including patients with germline *BRCA1* or *BRCA2* (g*BRCA*) mutations or with non-germline homologous recombination deficiency–positive tumors, the inhibition of PARP results in the production of double-strand breaks of DNA. Human DNA repair mechanisms largely rely on one intact copy of the gene. Cells with a double-strand break are usually targeted for cell death. This susceptibility of *BRCA*-deficient or *BRCA*-mutant cells to PARP inhibition, has spurred the clinical development of this class of agents. Initially, these agents were tested in women who had been pretreated with chemotherapy.

Other consolidation and/or maintenance therapy trials

Phase III trials of consolidation and/or maintenance therapy have been carried out with cytotoxic drugs, small molecules, vaccines, and radioimmunoconjugates with negative results. Extending the duration of paclitaxel has resulted in modest lengthening of PFS in randomized trials but was not adopted as a standard treatment after a subsequent trial.

Treatment options under clinical evaluation

Trials are ongoing with antiangiogenic drugs (other than bevacizumab) and with PARP inhibitors. PARP is a family of enzymes involved in base-excision repair of DNA single-strand breaks. In patients with homologous recombination deficiency, including patients with germline *BRCA1* or *BRCA2* (g*BRCA*) mutations or with non-germline homologous

recombination deficiency–positive tumors, inhibition of PARP results in production of double-strand breaks of DNA. Human DNA repair mechanisms largely rely on one intact copy of the gene; cells with a double-strand break are usually targeted for cell death. This susceptibility of *BRCA*-deficient or *BRCA*-mutant cells to PARP inhibition has spurred the clinical development of this class of agents. Sensitivity to platinum compounds is a feature of homologous recombination deficiency, and a population of platinum-sensitive patients is expected to be homologous recombination deficiency enriched and most likely to benefit from PARP inhibition.

Treatment of Recurrent or Persistent Ovarian Epithelial Cancer

Approximately 80% of patients diagnosed with ovarian epithelial cancer will relapse after first-line platinum-based and taxane-based chemotherapy and may benefit from subsequent therapies. Early detection of persistent disease by second-look laparotomies after completion of first-line treatment is no longer practiced. When the outcomes in institutions practicing such procedures (50% of institutions) were informally compared with the outcomes in institutions not using such procedures, lack of support for second-look laparotomies grew.

However, the practice of close follow-up of patients completing treatment by measuring cancer antigen 125 (CA-125) levels at intervals of 1 to 3 months was nearly universally adopted. In patients who are in clinical complete remission, increases in CA-125 from their initial treatment represent the most common method to detect disease that will eventually relapse clinically.

Treatment based on abnormal increases in CA-125 in the absence of symptoms or imaging evidence of disease has been addressed in a clinical trial.

Treatment Options for Patients with Recurrent or Persistent Ovarian Epithelial Cancer, FTC, and PPC

Drug treatment options for patients with recurrent disease are subdivided as follows:

1. Platinum-sensitive recurrence: For patients whose disease recurs more than 6 months after cessation of the induction, re-treatment with a platinum or platinum-containing combination, such as carboplatin, should be considered.
2. Platinum-refractory or platinum-resistant recurrence: For patients who progress before cessation of induction therapy (platinum refractory) or within 6 months after cessation of induction therapy (platinum resistant), platinum therapy is generally not useful as part of the treatment plan. Clinical trials should be considered.
   Other agents that have shown activity in phase II trials are listed in Table 4 and may also be used alone or in combination with other drugs, but such treatments are best done in prospective trials. Cytoreduction may be used; this intervention has been studied in the setting of randomized clinical trials.

The role of radiation therapy in patients with recurrent ovarian cancer has not been defined.

Platinum-sensitive recurrence

Platinum-containing chemotherapy regimens

On the basis of improved survival with etoposide or fluorouracil, carboplatin was approved in 1987 for the treatment of patients with ovarian cancer whose disease recurred after treatment with cisplatin. In a randomized phase II trial of paclitaxel, a currently used second-line drug, the cisplatin-containing combination of cisplatin plus doxorubicin plus cyclophosphamide, yielded a superior survival outcome. This study and subsequent studies have reinforced the use of carboplatin as the treatment core for patients with platinum-sensitive recurrences. Cisplatin is occasionally used, particularly in combination with other drugs, because of its lesser myelosuppression, but this advantage over carboplatin is counterbalanced by greater patient intolerance.

Oxaliplatin, initially introduced with the hope that it would overcome platinum resistance, has activity mostly in platinum-sensitive patients but has not been compared with carboplatin alone or in combinations.

With all platinum agents, outcome is generally better the longer the initial interval without recurrence from the initial platinum-containing regimens. Therefore, on occasion, patients with platinum-sensitive recurrences relapsing within 1 year have been included in trials of nonplatinum drugs. Several randomized trials have addressed whether the use of a platinum in combination with other chemotherapy agents is superior to single agents. Given its toxicity profile and noninferiority to the standard regimen, carboplatin plus pegylated liposomal doxorubicin is an important option for patients with platinum-sensitive recurrence. Carboplatin plus paclitaxel has been considered the standard regimen for platinum-sensitive recurrence in the absence of residual neurological toxic effects.

Bevacizumab, other targeted drugs, and poly (ADP-ribose) polymerase (PARP) inhibitors with or without chemotherapy

PARP is a family of enzymes involved in base-excision repair of DNA single-strand breaks. In patients with homologous recombination deficiency, including patients with germline *BRCA1* or *BRCA2* (g*BRCA*) mutations or with non-germline homologous recombination deficiency–positive tumors, inhibition of PARP results in production of double-strand breaks of DNA. Human DNA repair mechanisms largely rely on one intact copy of the gene; cells with a double-strand break are usually targeted for cell death. This susceptibility of *BRCA*-deficient or *BRCA*-mutant cells to PARP inhibition has spurred the clinical development of this class of agents. Sensitivity to platinum compounds is a feature of homologous recombination deficiency, and a population of platinum-sensitive patients is

expected to be homologous recombination deficiency-enriched and most likely to benefit from PARP inhibition.

Platinum-refractory or platinum-resistant recurrence

Chemotherapy

Clinical recurrences that take place within 6 months of completion of a platinum-containing regimen are considered platinum-refractory or platinum-resistant recurrences. Anthracyclines (particularly when formulated as pegylated liposomal doxorubicin), taxanes, topotecan, and gemcitabine are used as single agents for these recurrences on the basis of activity and their favorable therapeutic indices relative to agents listed in Table 4. The long list underscores the marginal benefit, if any, of these agents. Clinical trials should be considered for patients with platinum-resistant disease.

Drugs used to treat platinum-refractory or platinum-resistant recurrences include the following:

- **Paclitaxel.**
  Treatment with paclitaxel historically provided the first agent with consistent activity in patients with platinum-refractory or platinum-resistant recurrences. Patients generally received paclitaxel in front-line induction regimens. Re-treatment with paclitaxel, particularly in weekly schedules, had activity comparable with that of other drugs. Residual neuropathy upon recurrence may shift the choice of treatment towards other agents.
- **Topotecan.**
  Randomized studies have indicated that the use of topotecan achieved results that were comparable with those achieved with paclitaxel.
- **Pegylated liposomal doxorubicin.**
- **Docetaxel.**
  This drug has shown activity in paclitaxel-pretreated patients and is a reasonable alternative to weekly paclitaxel in the recurrent setting.
- **Gemcitabine.**
  Gemcitabine is an antimetabolite that was developed and approved in combination with platinum-based chemotherapy drugs and has shown activity as a single agent. Gemcitabine combined with cell cycle−targeted drugs and other drug combinations used in indications such as pancreatic and lung cancers are being explored.
- **Pemetrexed.**

Pemetrexed combined with gemcitabine has had unconvincing results compared with either agent alone. More studies are forthcoming that target cell cycle derangements common in certain genomic subtypes of ovarian cancer. Specifically, gemcitabine is presumed to be more active when there is loss of G1/S checkpoint from *TP53* mutations, CCNE1 amplification, RB1 loss, or CDKN2A mRNA downregulation.

Chemotherapy and/or bevacizumab

Immune checkpoint inhibitors

- **Avelumab.**
  Avelumab, an antibody targeting programmed death-ligand 1 (PD-L1), was studied alone or in combination with pegylated liposomal doxorubicin chemotherapy followed by chemotherapy alone in patients with platinum-resistant or refractory ovarian cancer.
- **Durvalumab.**
  Early phase studies have evaluated the use of other immune checkpoint inhibitors (e.g., durvalumab) with pegylated liposomal doxorubicin in patients with platinum-resistant recurrent disease.

Other drugs used to treat platinum-refractory or platinum-resistant recurrence (efficacy not well defined)

The drugs shown in Table 4 are not fully confirmed to have activity in a platinum-resistant setting, have a less desirable therapeutic index, and have a level of evidence lower than C3.

Table 4. Other Drugs That Have Been Used in the Setting of Recurrent Ovarian Cancer *(Efficacy Not Well Defined After Failure of Platinum-Containing Regimens)*

Drugs	Drug Class	Major Toxicities	Comments
Etoposide	Topoisomerase II inhibitor	Myelosuppression; alopecia	Oral administration; rare leukemia lessens acceptability and dampens interest

Drugs	Drug Class	Major Toxicities	Comments
Cyclophosphamide and several other bis chloroethyl amines	Alkylating agents	Myelosuppression; alopecia (only the oxazaphosphorines)	Leukemia and cystitis; uncertain activity after platinum agents
Hexamethylmelamine (Altretamine)	Unknown but probably alkylating prodrugs	Emesis and neurological toxic effects	Oral administration; uncertain activity after platinum agents
Irinotecan	Topoisomerase I inhibitor	Diarrhea and other gastrointestinal symptoms	Cross-resistant to topotecan
Oxaliplatin	Platinum	Neuropathy, emesis, myelosuppression	Cross-resistant to usual platinum agents, but less so
Vinorelbine	Mitotic inhibitor	Myelosuppression	Erratic activity
Fluorouracil and capecitabine	Fluoropyrimidine antimetabolites	Gastrointestinal symptoms and myelosuppression	Capecitabine is oral; may be useful in mucinous tumors
Tamoxifen	Antiestrogen	Thromboembolism	Oral administration; minimal activity, perhaps more in subsets

2. OBJECTIVES

The objectives of the 2021 Diagnosis Year Patterns of Care Study are to:

2.1. Describe the use of recommended biomarker tests which shall be verified with the treating physician/physician office staff or with unified medical record (record with all inpatient and outpatient records in a single file) or complete medical records (inpatient and outpatient medical records from multiple hospitals/healthcare systems/medical practices that include all records of cancer treatment);

2.2. Describe the use of targeted therapy which shall be verified with the treating physician/physician office staff or with unified/complete medical records;

2.3. Describe the use of adjuvant therapy, which shall be verified with the treating physician/physician office staff or with unified/complete medical record;

2.4. Characterize the practice patterns in different communities;

2.5. Compare the patterns of treatment (surgery, radiation therapy, systemic therapy [chemotherapy, immunotherapy, hormonal therapy, targeted therapy], cryotherapy) over time and by age, sex, race/ethnicity, and insurance status;

2.6. Describe comorbidities and the effect of co-morbid conditions on treatment;

2.7. Describe treatment by hospital characteristics (i.e., for profit vs. not for profit, teaching vs. non-teaching, bed size, etc.);

2.8. Describe the use of diagnostic tests and compare their use by demographic variables and geographic region;

2.9. Describe the medical record documentation of discussions about palliative care; and

2.10. Describe the effects of the COVID-19 pandemic on cancer care and patient outcomes.

3. STUDY PLAN

3.1. Data collection will be of men with prostate cancer (stage I – IV) diagnosed between January 1, 2021 and December 31, 2021 and women with ovarian cancer (stage I – IV) including fallopian tube and peritoneal cancers diagnosed between January 1, 2021 and December 31, 2021.

3.2. All stage coding will be based on the AJCC 8th Edition Staging Manual and on the SEER 2021 Coding and Staging Manual.

3.3. To obtain more stable estimates, Blacks, Hispanics Asian/Pacific Islanders, and Native American/Alaskan Natives will be oversampled. Hispanic cases can be of any race. If a case has Hispanic ethnicity, the case should be in a Hispanic stratum rather than the stratum based on the case's race. Due to the small numbers, all American Indians and Native Alaskans will be sampled.

3.4. Data collection will include:

Re-abstraction from the medical record of all variables on the data abstraction form:

- Insurance status
- Co-morbid conditions
- Characteristics of the hospital providing treatment
    - Bed size
    - Approved residency training program
    - Ownership
        - Not-for-profit; For profit
        - Federal government
        - Government-nonfederal
- Biomarker tests/assays completed and biomarkers identified
- Type of biopsy/cytology
- Surgery and pathologic margins
- Tumor characteristics
- Radiation therapy, cryotherapy, and systemic therapy (targeted therapy, chemotherapy, immunotherapy, hormonal therapy)

Abstraction from the medical record of specific pilot study variables on the data abstraction form:

- Effects of the COVID-19 pandemic on cancer care and patient outcomes

Verification with the treating physician or physician's office staff or with unified/complete medical records

- Participation in clinical trials

- Specific treatments given or refusal of treatments
- Specific agents given
- Tumor mutation testing
- Receipt of and type of palliative care

4. TIMETABLE

4.1. Data collection can begin as soon as the 2021 case samples can be drawn.

4.2. Quality control activities will be conducted AS DATA ABSTRACTING PROGRESSES BUT **NOT** SIMULTANEOUSLY WITH CASE ABSTRACTION. That is, QC should not be performed for a particular case until the case has already been abstracted and it has been found to meet inclusion criteria for POC. A different registrar should complete the QC abstract. QC abstracts should be compared to the non-QC abstract in real-time by the registry to identify coding issues and discrepancies. QC data should be evaluated by the registry PRIOR to data submission.

4.3. All data must be submitted to Information Management Services by April 30, 2025.

5. SUBMISSION OF DATA

5.1. The data files from the electronic data abstracting tool should be uploaded to NCI DCCPS' Biomedical Computing Contractor via the POC portal in your registry's Groupspace. Please post the files in the POC 2021 folder.

6. QUALITY CONTROL

6.1. A blind re-abstraction of data on a random 5% sample of the cases is to be included for each cancer site.

6.2. The 5% sample of cases to be re-abstracted should be selected by the registry. The procedure used by each registry for selecting the sample should be available if questions should arise. Quality control activities will be conducted **AS DATA ABSTRACTING PROGRESSES**, but individual cases should not be QC abstracted until the original abstract is complete. A different registrar should complete the QC abstract. QC abstracts should be compared to the non-QC abstract in real-time by the registry to identify coding issues and discrepancies. The QC case should be marked "QC=1" in the QC Data Item, and uploaded with the other abstracts. Retraining of the abstracting staff shall occur as needed as the QC is performed. Submission of the quality control (duplicate abstracting of 5% of the abstracts) to Information Management Services, Inc. will be done with the April 2025 submission of the POC data.

6.3. The entire data acquisition form should be completed by a second abstractor without referring to the original data abstract. Data sources to be re-abstracted include the hospital records and the information obtained from the physician verification form (do not re-contact the physician).

6.4. Prior to submitting the quality control and the original data abstract, any discrepancies between abstracts should be reconciled. The corrected data will then appear on both the QC and the study abstract form. The QC record is coded "1" in the Quality Control Data Item, while the original is coded "0". Every record that is coded "1" will have a corresponding "0" (non-QC) record, but only 5% of non-QC records (0) will have a QC record (1).

7. CONFIDENTIALITY

7.1. For all cancer patients in the sample, the name will be known only to the registry (i.e., not be provided to the National Cancer Institute nor to Information Management Services) and communication about cases will be through the registry identification number.

7.2. Hospital characteristics will be assigned at the registry. Names of the hospitals will not be provided to the National Cancer Institute nor to Information Management Services. This will ensure the confidentiality of all hospitals.

7.3. Data analysis will be done by individuals who agree to maintain confidentiality.

7.4. In scientific publications, only aggregate statistics, which will preserve the confidentiality, will be presented.

7.5. Registries participating in POC agree that NCI/NIH personnel, registry PI's, and other researchers who have POC data use agreements approved by NCI will have access to these data for research purposes and will be able to link geographic variables to POC data using patients' state, county, zip code, or census tract. Unencrypted geographic characteristics (e.g., state, county, zip code, and census tract of residence) will remain at IMS and will not be shared with NCI or other researchers using these data. No attempts will be made to identify patients with linking of geographic-level information.

References

https://www.cancer.gov/types/prostate/hp/prostate-treatment-pdq

https://www.cancer.gov/types/ovarian/hp/ovarian-epithelial-treatment-pdq

POC DATA ACQUISITION MANUAL

SECTION II

PATIENT ELIGIBILITY

SECTION II - PATIENT ELIGIBILITY

CONTENTS

PATIENT ELIGIBILITY

1. PATIENT SELECTION

1.1. The sampling procedures and the proportion of cases to be sampled are outlined below.

1.1.1. Women diagnosed with Stage I-IV ovarian cancer between January 1, 2021 and December 31, 2021 will be sampled by race/ethnicity (defined below).

1.1.2. Men diagnosed with Stage I-IV prostate cancers between January 1, 2021 and December 31, 2021 will be sampled by race/ethnicity (defined below).

2. SAMPLING

2.1. Each registry will select cases from their database according to the sampling plan below. Cases will be sampled proportionately to the registry size. Non-Hispanic blacks, Hispanics, Asian/Pacific Islander and Native Alaskan/American Indians will be over-sampled to provide more stable estimates.

2.2. For registries using SEER*DMS, algorithms will be implemented within SEER*DMS to identify cases for the POC study. Registry staff will be able to review the cases identified by the POC algorithms in SEER*DMS; and registry staff will use extracts in SEER*Abs to identify cases for abstracting.

2.3. For registries not using SEER*DMS to sample cases, assign a random number between 0 and 1 to all eligible cases in your registry diagnosed from January 1, 2021 through December 31, 2021 separately for all eligible cases of prostate or ovarian cancer in your registry diagnosed from January 1, 2021 through December 31, 2021. The number of cases to be sampled divided by the total number of eligible cases will be your sampling fraction. If the case has a number less than or equal to your sampling fraction, X, the case will be included in the study. If the random number assigned is greater than your sampling fraction, the case will not be abstracted for the Patterns of Care study. For example, all ovarian cancer cases eligible for inclusion in the study would have a random number between 0 and 1 assigned. If the sampling fraction for ovarian cancer is 0.63 and case 10100001 were given the random number of 0.594, it would be included in the study. Its number is less than the sampling fraction number of 0.63. If case 10100001 were assigned the random number of 0.654, it would not be abstracted for this study because its number is greater than the 0.63 sampling fraction.

2.4. At some point during the study, it is likely that cases will be added to the registry's database after sampling has already been completed. To give these additional cases an opportunity to be included in the study, the registries should identify such patients. Registries using SEER*DMS can re-run the sampling extract. Registries not using SEER*DMS can add them to the appropriate Sampling File, and assign them random numbers between 0 and 1. All cases found after the initial sampling **MUST** be sampled in this way. These additional cases will not modify the sampling fractions already obtained for a given time interval. The basis for selection of these cases into the study will be the sampling fractions (i.e., if the fraction for a cancer site group or subgroup is 0.49, a case will be added to the appropriate Patterns of Care file if the assigned random number is 0.49 or less). **If one or more of these additional cases is found to be ineligible after selection into the study, do not replace them with another case. If there are more than 9 cases found to be ineligible, please discuss with NCI whether additional cases should be sampled.**

3. REPORTABLE CASES

3.1. Reportable cases are to be drawn from all cancer patients who are in the registry who meet study criteria (described below).

3.2. A reportable case is one that meets the following criteria:

3.2.1. Patient must have a microscopically confirmed invasive prostate cancer or ovarian cancer.

3.2.2. Patients must be age 20 or older at diagnosis.

3.2.3. Patients must have been diagnosed between January 1, 2021 and December 31, 2021 (including those diagnosed on Jan. 1 and Dec. 31).

3.2.4. Malignant neoplasms arising in the ICD-O Topography sites listed below are reportable to the POC study. See SEER Program Coding and Staging Manual 2021 for a list of reportable terms.

3.2.5. This must be the first cancer diagnosed for this patient except for basal cell or squamous cell carcinoma of the skin.

3.2.6. Patients are excluded if there are simultaneously diagnosed cancers of more than one site (e.g., a patient diagnosed with primary prostate and primary lung cancer simultaneously) or simultaneously diagnosed cancers in the same site (i.e., two or more different primary cancers in the same site).

3.2.7. Site-specific inclusion criteria are listed below.

4. PROSTATE CANCER CASES

4.1. Include only cases meeting the following criteria:

- Men only
- Histology code 81403 (adenocarcinomas)
- Primary site C61.9
- Behavior code 3 (malignant)
- Diagnostic Confirmation codes 1, 2, 4
- Adults only (age 20+)
- Included only if this is the first diagnosis of cancer
- AJCC Stage I, II, III, IV (2018 8th edition)

4.2. Exclude cases with the following specifications:

- Simultaneously diagnosed separate primary cancers
- Histology codes: All other histologies
- AJCC stage 0
- Stage: All unknown stage or unstaged cases

4.3. Details of Sampling

Site	Race/Ethnicity
Prostate	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN

5. OVARIAN CANCER CASES

5.1. Include only cases with the following criteria:

- Histology codes 8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461, 9014
- Primary site ICD-O C48.1 (specific parts of peritoneum); C48.2 (peritoneum, NOS); C56.9 (ovary); or C57.0 (fallopian tube)
- Grade 2, 3, or "high"
- Stage I – IV
- Women only
- Adults only (age 20+)
- Included only if this is the first diagnosis of cancer
- Behavior code 3 (malignant)
- Diagnostic Confirmation codes 1, 2, 4
- AJCC Stage I, II, III, IV (2018 8th edition)

5.2. Exclude cases with the following criteria:

- Simultaneously diagnosed separate primary cancers
- AJCC stage 0
- Grade 1 or "low"
- Other primary sites
- Histology Codes: All other histologies
- Unknown stage or unstaged patients

5.3. Details of sampling

Site	Race/Ethnicity
Ovary	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN

6. GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

6.1. Cases which are not reportable to the POC study are those with:

6.1.1. Exclusion criteria applied to the selection process:

- Neuroendocrine tumor (NET) histologies
- Lymphoma/hematopoietic histology M-9590/3-9993/3
- Unknown stage or unstaged cases

- Death certificate only diagnosis
- Autopsy only diagnosis
- Previous malignancies (except basal cell or squamous cell carcinoma of the skin)
- Simultaneously diagnosed cancers 60 days or less apart of the same site or of two different sites. Examples:
  - A patient simultaneously diagnosed with primary ovarian cancer and primary lung cancer within 60 days.
  - A patient diagnosed with two ovarian primaries within 60 days
  - A patient diagnosed with multiple simultaneous prostate primaries in different segments of the prostate
- Non-histologically proven diagnosis (clinical diagnosis only)
- Cases with age at diagnosis less than 20 years old

6.1.2 Exclusion criteria identified during the case abstraction process

- Cases with previously diagnosed neoplasms of uncertain or unknown behavior
- Cases previously diagnosed with GIST of malignant or unknown behavior
- Cases that are identified for POC but upon abstraction are found to be improperly coded such that when corrected do not meet POC criteria
- Cases that were reported via out-of-state data exchange or from VA facilities **and** for which there are no local (in-state) providers to contact and no medical records to access; cases reported via out-of-state data exchange but for which medical records are available should be included.
- Cases for which the registry has only a record of the cancer diagnosis or only pathology information and does not have any information on subsequent treatment or outcomes

7. REPORTABILITY SUMMARY BY SITE

7.1. Prostate cancer

- Include primary sites ICD-O-3 C61.9
- Include histology codes: 8140
- Include behavior code: 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include AJCC 8th Edition Stage I, II, III, IV

7.2. Ovarian cancer

- Include primary sites ICD-O-3 C48.1 (specific parts of peritoneum); C48.2 (peritoneum, NOS); C56.9 (ovary); or C57.0 (fallopian tube)
- Include histology codes: 8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461, 9014

- Include grade 2, 3, or “high”
- Include behavior code: 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include AJCC 8th Edition Stage II, III, IV

POC DATA ACQUISITION MANUAL

SECTION III

COMMON DATA SET

SECTION III – COMMON DATA SET

CONTENTS

SEER REGISTRY PARTICIPANT NUMBER

ITEM A-1

1. **Code:** 2 digits

2. **Description:**

   2.1. The SEER Institution Number consists of the 2-digit SEER PARTICIPANT Code used for annual submissions to NCI.

   2.2. See below for a list of participating Registries and their Participant Numbers.

Registry	Participant Number
Connecticut	02
Greater California	41
Iowa	22
Kentucky	42
Louisiana	43
New Mexico	23
Seattle	25
Utah	26

CASE NUMBER

ITEM A-2

1. **Code:** 8 digits

2. **Description:**

   2.1. The CASE NUMBER is the registry-specific patient identification number used on the files submitted to the National Cancer Institute.

   2.2. The CASE NUMBER is used for administrative purposes by NCI and for communication with the Registry concerning the case. Patient name and number assignment lists will be available only at the Registry.

   2.3. If you do not have a full eight digits, please code this exactly as you would for other data submissions.

QUALITY CONTROL (QC)

ITEM A-3

1. **Code:** 0 = No
   1 = Yes

2. **Description:**

   2.1. For each cancer site, a **random** 5% sample of cases to be re-abstracted should be selected by the registry. The procedure used by each registry for selecting this sample should be available if questions arise. QC activities should be conducted as data abstracting progresses, rather than waiting until the end of the data collection.

   2.2. If the randomly selected case includes information from a PVF, do not send a second PVF when performing QC. Use the first PVF received to complete the QC abstract.

   2.3. If a case is randomly selected for QC but both abstractors do not have access to medical records and it is not feasible for abstracting, then swap the case with another randomly selected case.

   2.4. The QC abstraction of a particular case must be performed ***after*** the original abstract is completed, to ensure the case is appropriate for inclusion in POC.

   2.5. Code "0" if this is **not** a re-abstracted QC case. Code "1" if it is a re-abstracted QC case.

   2.6. QC is to be done as the abstracting proceeds. **The goal of QC is to correct mistakes being made as the study progresses rather than waiting until all of the data have been incorrectly collected.** Therefore, a comparison between the original abstract and the QC abstract should be made at the time of completion of the QC form. Any discrepancies should be immediately addressed with the abstractor and it should be determined whether the abstractor or the QC person is correct. Once discrepancies are addressed, the appropriate correction should be made to the abstract or to the QC form and a full discussion should take place to be certain that the data is being accurately abstracted and coded. The abstract and the QC form should be reconciled before submission to IMS. The form with the incorrect data, whether it is the study abstract or the QC form, should be corrected so that both forms contain the same data.

QUALITY CONTROL (QC) (continued)

ITEM A-3

2.7. Steps to be taken:

1. Original abstract completed
2. QC abstract completed
3. Immediate comparison of the original and QC forms
4. Identification of differences between the original and QC
5. Determination of correct item or code
6. Discussion of correct abstracting or coding
7. Correction of original or QC abstract
8. Submit finalized QC and original abstracts

TUMOR RECORD NUMBER

ITEM A-4

1. **Code:** 2-digit code
   - 01 First record for a case
   - 02 Second record for a case
   - ..
   - ..
   - nn Last of nn records for a case

2. **Description:**

   2.1. This is the unique sequential number as assigned to the case being abstracted.

   2.2. This is the number that refers to the order in which the cancer was registered by the participating registry. This data item will not be edited. It is for registry use only and can be blank if it is not needed.

SEQUENCE NUMBER

ITEM A-5

1. **Code:** 2-digits

2. **Description**:

   2.1. The SEQUENCE NUMBER is the number of this primary in the life history of the patient. This is the SEQUENCE NUMBER as assigned for SEER submissions.

   2.2. For prostate and ovarian cancer cases, only “00” and “01” will be eligible since these cancers will be first primary cancers for all cases included in POC.

PRIMARY SITE

ITEM A-6

1. **Code**: 3 digits

2. **Description**:

   2.1. The Topography section of the International Classification of Disease for Oncology, Third edition (ICD-O-3, 2001) is used for coding the primary site of all solid tumors.

   2.2. The coding of primary site is to be completed as described in *The SEER Program Coding and Staging Manual 2021*, Section IV, Primary Site.

   2.3. The 'C' should not be coded and the decimal point should be disregarded.

DIAGNOSTIC CONFIRMATION

ITEM A-7

1. **Code**: Microscopically Confirmed
   1 = Positive histology
   2 = Positive cytology
   4 = Positive microscopic confirmation, method not specified

2. **Description**:

   2.1. **Eligible codes for Patterns of Care include only microscopically or positive laboratory test/marker study confirmed diagnosis codes 1, 2, and 4.** These cases must have their cancers microscopically confirmed.

   2.2. Code diagnostic confirmation as described in the SEER Program Coding and Staging Manual 2021, Section IV, Diagnostic Confirmation.

   2.3. No case diagnosed only at autopsy or by death certificate would be eligible.

HOSPITAL CODE

ITEM A-8

1. **Code:** 7 digits

2. **Description**:

2.1. This item will be assigned by the participating registry to the hospital of most definitive surgery or, if no surgery, the most definitive therapy in hierarchical order of radiation then systemic therapy. The codes are used to describe the hospital characteristics and will be obtained by coders from the American Hospital Directory at https://www.ahd.com/search.php.

2.2. On the American Hospital Directory webpage (https://www.ahd.com/search.php), enter the Hospital Name, State, or Zip Code for the hospital and click Submit. If more than one hospital is listed in the Table of Search Results, select the relevant Hospital Name.

2.3. The following fields should be coded from the AHD hospital profile:

- Type of Control (Hospital Ownership) is listed under "Identification and Characteristics" of the Free Profile
- Total Staffed Beds (Bed Size) is listed under "Identification and Characteristics" of the Free Profile
- Patient Experience Rating is listed under "Identification and Characteristics" of the Free Profile
- Teaching Status (Approved Residency Training) is found in the Free Profile
- TPS (Total Performance Score) Quality Score, found in the table "Value-based Purchasing Program" in the "Quality" section.

2.4. Commission on Cancer (CoC) Hospital Accredited should be looked up from the ACS website: https://www.facs.org/hospital-and-facilities. Select "Cancer Program" from the dropdown and search for a hospital either by entering State, City or Zip, or entering the name of the hospital.

2.5. Hospital Urban/Rural Status codes are searchable here: https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/

Download the 2010 Rural-Urban Commuting Area (RUCA) Codes, ZIP Code File (an Excel file) here: https://www.ers.usda.gov/webdocs/DataFiles/53241/RUCA2010zipcode.xlsx?v=3520

Find the RUCA codes provided for hospitals in the relevant zip codes. Translate these RUCA codes into urban (1), rural (2), or unknown (9) status as follows:

RUCA codes 1-7 = Urban (1)

RUCA codes 8-9 = Rural (2)

RUCA codes 88, 99 = Unknown (9)

2.6. A patient seen in more than one institution/hospital should be assigned only one HOSPITAL CODE, that of the hospital providing the most definitive treatment as described above.

2.7. The HOSPITAL CODE is used to describe the characteristics of the hospitals/institutions while maintaining the confidentiality of each.

2.8. The HOSPITAL CODE is comprised of the seven components below. If no information on any of the seven components of the HOSPITAL CODE is available, code that component as 9 = Unknown. If a hospital is not listed, code the hospital as

9 9 9 9 9 9 9

Digit 1: Bed size code:

1 = 1 - 49 beds

2 = 50 - 99 beds

3 = 100 - 199 beds

4 = 200 - 299 beds

5 = 300 - 399 beds

6 = 400 - 499 beds

7 = 500 or more beds

8 = OPD, including doctor's office or other non-hospital outpatient setting, including facilities with zero beds

9 = Unknown

Digit 2: Approved Residency training

0 = No

1 = Yes (MD or DO training program)

9 = Unknown

Residency training approval by the Accreditation Council for Graduate Medical Education. A physician's office should be coded "0- No."

Digit 3: Hospital Ownership (type of control) code:

1 = Non-Profit – Church
2 = Non-Profit – Private
3 = Non-Profit – Other
4 = Proprietary
5 = Government – Federal
6 = Government – State
7 = Government – Local
8 = Government – Hosp. Dist. Or Auth
9 = Unknown

Digit 4: TPS (Total Performance Score) Quality Score
1 = 0 – 24.250
2 = >24.250 - 29.750
3 = >29.750 - 35.125
4 = >35.125 – 42.834
5 = >42.834
9 = Unknown

Digit 5: Patient Experience Rating:
1 = 1 star
2 = 2 stars
3 = 3 stars
4 = 4 stars
5 = 5 stars
9 = Unknown

Digit 6: Commission on Cancer (CoC) Hospital Accredited
0 = No
1 = Yes
9 = Unknown

Digit 7: Hospital Urban/Rural Status
1 = Urban
2 = Rural
9 = Unknown

2.9. Each hospital will have a seven-digit code that will include one code for each of these items above. These codes will be assigned by the registry. For example, a 300-bed hospital with an approved residency program that is a non-profit private hospital, has a TPS score of 40.800, a 3-star Patient Experience Rating, is not CoC accredited, and is Urban would be coded as:

5 1 2 4 3 0 1

2.10. There will be one code for each hospital/institution. However, these codes will not necessarily be unique. Your registry area may have several hospitals with the same characteristics. It is possible that there may be several 100-199 beds hospitals with no residency training program that are proprietary, have TPS scores between 24.250 - 29.750, have 4-star patient experience ratings, are CoC accredited, and are Urban. The 7-digit code for all of these hospitals would be:

3 0 4 2 4 1 1

2.11. If a patient is seen only in a physician's office and is never treated in a hospital as an inpatient or outpatient, code the bed size as 8, OPD. TPS Quality Score, Patient Experience Rating, Commission on Cancer Hospital Accreditation status, and Hospital Urban/Rural Status should all be coded as 9, "Unknown". The physician practice ownership (digit 3 of the hospital code) may be non-profit, proprietary, government, or unknown. If the physician practice ownership is not specified, in the available medical records, code as 9, "Unknown".

To summarize, for non-hospitals, code the digits as follows:

Digit 1: code as 8
Digits 2 and 3: can be coded if known
Digits 4-7: code as 9

INSURANCE STATUS

ITEM A-9

1. **Code**: 0 = No

   1 = Yes

   2 = Patient died within 30 days of diagnosis (response option for >30 days after diagnosis only)

   3 = Yes, but coverage dates unknown

   9 = Unknown

   Code separately for:

   - At or within 30 days of diagnosis (≤ 30 days)
   - More than 30 days after diagnosis (> 30 days)

   - ☐ No insurance/Self pay
   - ☐ Medicare fee-for-service (FFS), which may be listed as Part A, Part A/B, or Medicare unspecified
   - ☐ Medicare HMO, which may be listed as Medicare Advantage, Medicare managed care, or Medicare Part C
   - ☐ Medicare Part D or Medicare prescription drug plan (PDP)
   - ☐ Supplemental private insurance with Medicare plan, which may be listed as Medigap insurance (select only if patient also has Medicare coverage)
   - ☐ Medicaid
   - ☐ Medicaid Pending
   - ☐ Private Insurance/IPA Plan/HMO or Managed Care Plan Not Including Medicare or Medicaid
   - ☐ Tricare/Other Military *Not Including Veterans Affairs (VA)*
   - ☐ Veterans Affairs (VA)
   - ☐ IHS (Indian Health Service)
   - ☐ Other (specify)_____

2. **Description**:

   2.1. This item is used to code information on all insurance coverage reported by the patient and has two parts; all insurance coverage reported **at or within 30 days** of diagnosis, and separately all insurance coverage reported **more than 30 days after** diagnosis. Cases may have more than one types of insurance. Code all appropriate insurance carriers on the abstract form. Please try to determine insurance status as accurately as possible because insurance status influences selection of therapy for cancer patients.

INSURANCE STATUS (continued)

ITEM A-9

2.2. Patients may have codes of "1 – Yes" for multiple types of insurance. For example, a patient with both Medicare and Medicaid insurance would be coded as having "1 – Yes" for both their specific type(s) of Medicare insurance and for Medicaid insurance. If a patient has the same insurance at diagnosis and >30 days after diagnosis, it should be coded as "1 = Yes" for both the "at or within 30 days" as well as the "More than 30 days" fields.

2.3. If a patient is listed as having a specific type or types of insurance (e.g., Medicaid), please code all other types of insurance as "0 = No". If a patient is listed as being insured but the type of insurance is not specified or is unknown, please code "No insurance/Self pay" as "0 = No", each other type of insurance as "9 = Unknown", and specify "insured, type unknown" under "Other (specify)".

2.4. Code "1 – Yes" for No Insurance when it is stated in the medical record that a patient has no insurance coverage or is a self-pay. If the medical record states that a patient subsequently has insurance during the same time period (30 days or less after diagnosis vs. more than 30 days after diagnosis), the type(s) of insurance specified should also be indicated by "1 – Yes". If a patient has insurance at diagnosis and subsequently loses all insurance, code "1 – Yes" for No Insurance in addition to coding "1 – Yes" for other insurance that the patient previously had during the time period.

2.5. For patients with Medicare insurance, code "1 – Yes" for Medicare HMO if they are listed as having Medicare Advantage insurance (which is also called Medicare managed care or Medicare Part C). If patients are listed as having Medicare insurance or the type of Medicare plan is not specified, code "1 – Yes" for Medicare fee-for-service (FFS).

2.6. Medicare patients may also have a separate Medicare prescription drug plan, which is also known as Medicare Part D. For these patients, both their main Medicare insurance and Medicare Part D should be coded "1 – Yes".

2.7. For patients with Medicare insurance and private insurance (sometimes called Medigap insurance), both their main Medicare insurance the "Supplemental private insurance with Medicare plan" should be coded "1 – Yes". "Supplemental private insurance with Medicare plan" should be coded "1 – Yes" only for patients who also have another type of Medicare insurance.

INSURANCE STATUS (continued)

ITEM A-9

2.8. Code “1 – Yes” for Medicaid if the patients is listed as having Medicaid (not otherwise specified) or any type of Medicaid coverage (e.g., Medicaid HMO or Medicaid managed care). Code “1 – Yes” for Medicaid Pending if the patient is listed as having applied for Medicaid or that Medicaid coverage is pending. Do not code “1 – Yes” for Medicaid Pending if the patient is uninsured and there is no mention of applying for Medicaid coverage or Medicaid coverage being pending.

2.9. Code “1 – Yes” for private insurance when the patient is reported to have a private insurance carrier such as Blue Cross, Travelers, Aetna, whether or not this is an HMO or managed care program, including an IPA. As stated in (2.6), individuals with Medicare and private insurance should have codes of “1 – Yes” for both their main type of Medicare insurance and Supplemental private insurance with Medicare plan”. Individuals with “Supplemental private insurance with Medicare plan” should not also have private insurance coded as “1 – Yes” unless their insurance changed from private insurance to Medicare coverage.

2.10. A small number of patients may utilize services provided by the Indian Health Service (IHS). Code “1 – Yes” when the patient has information in the medical record of receiving services provided by IHS.

2.11. If a patient died within 30 days of diagnosis, code all insurance types for more than 30 days after diagnosis (> 30 days) as “2 = Patient died within 30 days of diagnosis”.

2.12. If it is known that the patient had a specific type of insurance, but the coverage dates are unknown, code “3” in both time periods.

2.13. Code "9 - Unknown, not stated" to all when there is no insurance carrier information in the patient's medical record.

Specifics:

2.14. Medicaid is insurance provided by the state and supplemented by the federal government for those who are low-income, on welfare, or are medically indigent (i.e., cannot afford to pay their medical bills although they are not on welfare). Some states may use a term other than Medicaid for their program: e.g., California has a program called "MediCal." Please verify the name of the Medicaid program in your state. If the hospital has noted that “Medicaid is pending,” code Medicaid as “1 – Yes.” Patients with Medicaid do not usually have any other insurance except for some patients on Medicare. If Medicaid is coded “1 – Yes,” then all other insurance variables will most likely be coded “0 – No.”

INSURANCE STATUS (continued)

ITEM A-9

2.15. Blue Cross/Blue Shield is one of the most common non-governmental insurance carriers. There are many other similar companies, such as Aetna, Prudential, Travelers, UnitedHealthcare, Cigna, Humana, etc. These companies offer a variety of insurance plans including HMOs (Health Maintenance Organizations, also referred to as managed care), IPAs (Independent Practice Associations), and other plan types. These companies may also provide Medicare or Medicaid coverage. Therefore, having Blue Cross/Blue Shield or a similar company listed does not necessarily mean private insurance. Determine the type of insurance (private, Medicare, or Medicaid) provided for the patient and code appropriately.

2.16. Tricare/Other Military vs. VA: Tricare is a comprehensive insurance plan provided by the federal government for retired military and diplomatic personnel and their dependents. This form of health insurance was previously known as CHAMPUS. VA (Veterans Affairs) is different from Tricare; this coverage entitles patients to treatment at no cost at VA hospitals. Code Tricare/Other Military as "1 – Yes" if the patient has this type of insurance; code VA as "1 – Yes" if the patient received care at a VA facility.

Examples:

2.17. Patient with Medicare and supplemental Blue Cross/Blue Shield private insurance: Code "1 – Yes" to both Medicare and Supplemental private insurance. Patients who have only Medicare managed care/HMO insurance that is administered by Blue Cross/Blue Shield should have "1- Yes" coded ONLY for "Medicare HMO".

2.18. Patient who has documentation in the record that no insurance coverage is available: Code "1 – Yes" to no insurance and code all others "0 – No."

2.19. Patient who has no information available in the record regarding insurance coverage: Code "9 – Unknown" to all types of insurance.

2.20. If Medicaid pending is coded as "1 – Yes". It is unlikely that the patient has any other type of insurance, although they may be pending for enrollment in a Medicaid managed care program.

TREATMENT PROTOCOL REGISTRATION

ITEM A-10

1. **Code**: 0 = Not registered on treatment protocol (clinical trial)
   1 = Registered on treatment protocol during first course of therapy
   2 = Registered on treatment protocol during after course of therapy
   3 = Registered on treatment protocol during and after first course of therapy
   7 = Patient or patient's guardian refused treatment protocol
   8 = Treatment protocol participation recommended, unknown if registered
   9 = Unknown, not stated

2. **Description**:

   2.1. Code whether the patient was registered on a treatment protocol (clinical trial) at any time following cancer diagnosis. This includes treatment protocols sponsored by cooperative groups, clinical cancer centers, comprehensive cancer centers, and drug companies. This includes registration in protocols to treat cancer or to treat cancer-related symptoms (e.g. fatigue).

   2.2. If a patient is registered on a non-therapeutic protocol (pain control, for instance, cancer control, or other protocol), but is not participating in a treatment protocol, code this item as "0 - Not registered on treatment protocol."

   2.3. Code "0 - Not registered on a treatment protocol" when it is known that the patient was not registered on a treatment protocol during the first course of therapy.

   2.4. Code "1 - Registered on treatment protocol during first course of therapy" when the patient was registered on a treatment protocol during the first course of therapy. Code "2 - Registered on treatment protocol after the first course of therapy" when the patient was registered on a treatment protocol after the first course of therapy. Code "3 - Registered on treatment protocol during and after first course of therapy" when the patient was registered on two or more different treatment protocols, at least one during the first course of therapy and at least one after the first course of therapy.

   2.5. Code "7 - Patient or patient's guardian refused protocol" when a treatment protocol was recommended, but the patient was not registered due to patient/guardian refusal.

   2.6. Code "8 - Treatment protocol participation recommended, unknown if registered" when a treatment protocol was recommended, but it is unknown whether the patient was actually registered.

   2.7. Code "9 - Unknown, not stated" when there is no documentation regarding registration on a treatment protocol.

TREATMENT PROTOCOL SPONSOR AND NUMBER

ITEM A-11

1. **Code**: 1 to 12 characters representing the Treatment Protocol Sponsor such as cooperative group, research base, Clinical Cancer Center, or Comprehensive Cancer Center and the Protocol Number.

2. **Description**:

   2.1. "Treatment Protocol Sponsor" identifies the research base or cooperative group that is conducting the first clinical trial in which the patient was enrolled. When the patient was entered through an intermediate research base, the actual sponsoring group should be recorded. "Treatment Protocol Number" identifies the specific treatment protocol. If the patient was enrolled in more than one treatment protocol, code only the first.

   2.2. **Code letters and digits only**, eliminating all punctuation such as hyphens, slashes, periods, and spaces.

   2.3. If a patient was not registered on a treatment protocol, record "9" in the first (left) code box on the form. If A-10 is coded “0”, “7”, “8”, or “9”, then A-11 should be coded with a single “9” in the left most box and the other boxes in A-11 should be left blank.

   2.4. The Treatment Protocol Sponsor and Number should be left-justified and the remaining code spaces left blank.

   2.5. If a patient is registered on a local treatment protocol, record "LOCAL."

   2.6. If a patient is registered on a drug company treatment protocol, record the name of the drug company.

   2.7. If the protocol sponsor and number are unknown, then A-11 should be coded with a single “9” in the left most box and the other boxes in A-11 should be left blank.

   2.8. **For this item record the protocol sponsor and number, not the clinical trial registration number.**

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-11

Examples:

SWOG 8711 is coded:

S W O G 8 7 1 1 _ _ _ _

Sponsor: SWOG Number: 8711

Local protocol is coded:

L O C A L _ _ _ _ _ _ _

Drug company protocol is coded:

ASTRAZENECA _

Sponsor: AstraZeneca

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF

ITEM A-12

1. **Code**: 0 = No outpatient verification and unified/complete medical record not available
   1 = Yes, physician or office staff
   2 = Unified or complete (inpatient and outpatient) records reviewed
   3 = Death prior to discharge from hospitalization for initial cancer treatment
   4 = Discharge from hospitalization for initial cancer treatment to hospice

2. **Description**:

   2.1. This item will allow investigators to determine whether the case information recorded has been **verified by a source other than only the hospital medical record.**

   2.2. Unified medical record refers to a record with all inpatient **and** outpatient records in a single file. Complete medical records refers to inpatient **and** outpatient medical records from multiple hospitals/healthcare systems/medical practices that include all records of cancer treatment. If you have reviewed unified/complete medical records, there is no need to send a physician verification form. Code "2 = Unified or complete records review" should take priority. That is, if unified/complete medical records are reviewed, code "2 = Unified or complete records review" should always be indicated for this item.

   2.3. In the case of facilities such as HMOs or hospitals with both inpatient and outpatient records documenting all cancer treatment, reviewing this record would be equivalent to reviewing the physician's office records. Code these cases as "2 –Unified or complete records review."

   2.4. For cases that were not treated at facilities with unified medical records (i.e., both inpatient and outpatient records including all cancer treatment the patient received for a single facility or healthcare system), **but inpatient and outpatient records are available for all facilities/healthcare systems where any cancer treatment occurred, also code these cases as "2 – Unified or complete records review."**

   2.5. If unified/complete medical records are not available **and** the medical record indicates the patient was hospitalized prior to initiation of cancer therapy and died during this hospitalization, code this Item as "3 = Death prior to discharge from hospitalization for initial cancer treatment ".

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF (cont)

ITEM A-12

2.6. If unified/complete medicals record are not available **and** the patient was not hospitalized and died prior to initiation of cancer therapy (code “3”) **and** the medical record indicates that the patient was hospitalized prior to initiation of cancer therapy and was then discharged to hospice, code this item as "4 = Discharge from hospitalization for initial cancer treatment to hospice". For codes “3” or “4”, physician verification is not required and the abstraction is in the same category as if unified/complete medical records were used.

2.7. If a case is not verified with unified/complete medical records, death prior to hospital discharge, or discharge to hospice (codes “2”, “3”, or “4”) and the patient was diagnosed and/or treated at more than one hospital or outpatient facility, attempts should be made to obtain medical records from all treating hospitals/outpatient facilities regardless of location (i.e., both in-state and out-of-state). If a patient was diagnosed at one hospital and treated at another hospital, the treating hospital may have copies of the diagnosis records; therefore, it may not be necessary to obtain these records from the diagnosing hospital.

2.8. If the case information was verified through contact with a physician or physician office staff, code "1 – Yes, physician or office staff.” **The contact may be the physician’s response to a letter or a telephone contact with the physician or office staff, or a review of the physician's office records by a POC abstractor.**

2.9. If a case is not verified with unified/complete medical records, death prior to hospital discharge, or discharge to hospice (i.e., options 2, 3, or 4 do not apply) and the patient was treated by more than one oncologist, verification forms should be sent to all treating oncologists regardless of location (i.e., both in-state and out-of-state). If at least one of the treating oncologists completes and returns the verification form, this item can be coded as being verified “1= Yes, physician or office staff”, and a **comment should be included with the item (in the comment field that goes to NCI) indicating the number of treating oncologists/oncology practices and the number of oncologists/oncology practices who provided verification information.**

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF (cont)

ITEM A-12

2.10. If the case information was not verified by the physician or office staff, there was no review of the patient's unified/complete medical records, and the patient neither died during an initial treatment hospitalization prior to discharge nor was discharged to hospice after an initial hospitalization, then code this item as "0 – No outpatient verification and unified/complete records not available." This might be the case if the hospital medical records cannot be found. Also use code "0" if the individual was a "VA patient only" and access to the medical records has been denied by the VA. (Some registries are allowed access while other VA systems will not provide information to the registry.) Please document in the "comment" column of the POC abstracting software if you were not allowed access to medical records.

HEIGHT / WEIGHT

ITEM A-13

1. **Code**: Height

030-998 = Actual height
999 = Unknown/not recorded

Units

1 = Inches (in)
2 = Centimeters (cm)
3 = Other specify
9 = Unknown/not stated

Weight

010-998 = Actual body weight
999 = Unknown/not recorded

Units

1 = Pounds (lbs)
2 = Kilograms (kg)
3 = Other specify
9 = Unknown/not stated

PLEASE BE CERTAIN TO RECORD THE UNITS OF ALL OF THESE MEASURES.

2. **Description**:

2.1. Body mass, overweight and obesity have been associated with certain types of cancer. Of particular concern is whether those who are overweight or obese are receiving appropriate therapy which will decrease the disparity in survival rates. ASCO reports that as many as 40% of obese patients do not receive systemic therapy based on their weight. The ASCO has established guidelines for physicians to consider actual weight rather than ideal weight to determine dose.

HEIGHT / WEIGHT (continued)

ITEM A-13

2.2. Record the height of the patient. Round height to the nearest whole number if a decimal point has been recorded. Record the unit of measure, inches or cm. If it is unknown or not stated which unit of measure is used, then record “9 = unknown.”

2.3. Record the patient weight from the medical record. This is a difficult variable to find in the record. Please record weight closest to the time of treatment, if possible, since the concern is the appropriate dose of chemotherapy. If weight at diagnosis is not available, then record “usual” weight if stated. Round weight to the nearest whole number if a decimal point has been recorded.

2.4. Record the units of measure for each item. They are extremely important in calculating body mass or obesity. Do not convert from one unit of measure to another, i.e. kilograms to pounds.

DATE OF FIRST ONCOLOGIST CONSULTATION

ITEM A-14

1. **Code**: Date of FIRST oncologist appointment or consultation following cancer diagnosis

   MM-DD-YYYY

   00-00-0000 – Patient did not have an appointment or consultation with an oncologist following cancer diagnosis

   99-99-9999 – Date not available in medical record for first oncologist appointment or consultation

2. **Description**:

   2.1. Record the date specified in the medical record for the patients first appointment or consultation with an oncologist following cancer diagnosis. This could be any meeting with a medical oncologist, surgical oncologist/cancer surgeon, or radiation oncologist on or after the date of definitive cancer diagnosis. The appointment or consultation could be inpatient or outpatient. If the patient did not have any appointments or consultations with an oncologist following cancer diagnosis, record the date as 00-00-0000. If the patient did have an appointment or consultation with an oncologist following cancer diagnosis but the date of this is not specified, code the date as 99-99-9999.

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE

ITEM A-15

1. **Code**: 1 digit each

A. Patient diagnosed with COVID-19 following cancer diagnosis

0 No diagnosis of COVID-19 following cancer diagnosis listed in medical record (Code dates below as 00-00-0000)
1 COVID-19 diagnosis following cancer diagnosis listed in medical record

B. Date of FIRST positive COVID-19 diagnosis following cancer diagnosis

MM-DD-YYYY
00-00-0000 – COVID-19 diagnosis not listed in medical record
99-99-9999 – Date not available for first COVID-19 diagnosis in medical record

C. Date of FIRST hospital admission for COVID-19 following cancer diagnosis

MM-DD-YYYY
00-00-0000 – COVID-19 diagnosis not listed in medical record
88-88-8888 – Patient diagnosed with COVID-19 but no hospital admission for COVID-19 listed in medical record
99-99-9999 – Date not available for first hospital admission for COVID-19

D. Impact of COVID-19 pandemic on patient's definitive cancer diagnosis

0 No impact of COVID-19 on definitive cancer diagnosis specified in medical record
1 Cancer diagnosis delayed due to COVID-19
8 Other impact to cancer diagnosis due to COVID-19 (specify) _____

E. Impact of COVID-19 pandemic on patient's first cancer surgery to the primary site

0 No impact of COVID-19 on first cancer surgery to the primary site specified in medical record
1 First surgery to the primary site was delayed
2 First surgery to the primary site was altered
3 First surgery to the primary site was canceled
4 Patient refused first cancer surgery to the primary site due to COVID-19
8 Other impact to surgery due to COVID-19 (specify) _____
9 Patient did not receive surgery to the primary cancer site for reasons other than COVID-19

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE (cont)

ITEM A-15

F. Impact of COVID-19 pandemic on patient's first course of radiation therapy to the primary site

0 No impact of COVID-19 on first course of radiation therapy to the primary site specified in medical record
1 First course of radiation therapy to the primary site was delayed
2 First course of radiation therapy to the primary site was altered
3 First course of radiation therapy to the primary site was canceled
4 Patient refused first course of radiation therapy due to COVID-19
8 Other impact to radiation due to COVID-19 (specify) _____
9 Patient did not receive radiation therapy to the primary cancer site for reasons other than COVID-19

G. Impact of COVID-19 pandemic on patient's first course of systemic therapy

0 No impact of COVID-19 on first course of systemic therapy specified in medical record
1 First course of systemic therapy to the primary site was delayed
2 First course of systemic therapy to the primary site was altered
3 First course of systemic therapy to the primary site was canceled
4 Patient refused first course of systemic therapy due to COVID-19
8 Other impact to systemic therapy due to COVID-19 (specify) _____
9 Patient did not receive systemic therapy for reasons other than COVID-19

H. Impact of COVID-19 pandemic on patient's palliative care

0 No impact of COVID-19 on palliative care specified in medical record
1 Palliative care was delayed
2 Palliative care was altered
3 Palliative care was canceled
4 Patient refused palliative care due to COVID-19
8 Other impact to palliative care due to COVID-19 (specify) _____
9 Patient did not receive palliative care for reasons other than COVID-19

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE (cont)

ITEM A-15

2. **Description**:

2.1. This item collects information on impact of the COVID-19 pandemic on the patient's cancer care specified in the medical record. This could include mention in the medical record of "COVID" or "coronavirus". To complete this section, review the following sections of the medical record (when present): assessment and plan from oncology and palliative care clinician notes; oncology history from any clinician notes; palliative care notes; and chemotherapy and radiation therapy flow sheets

2.2. In **Item A**, record whether the medical record indicates that the patient was diagnosed with COVID-19 after the date of cancer diagnosis. In **Item B**, record the date of COVID-19 diagnosis. If the patient was not diagnosed with COVID-19 following cancer diagnosis, record the date as 00-00-0000. If the patient was diagnosed with COVID-19 after cancer diagnosis but the date of COVID-19 diagnosis is not specified, code the date as 99-99-9999.

2.3. In **Item C**, record the date of the first hospital admission due to COVID-19 after the date of cancer diagnosis. If the patient was not diagnosed with COVID-19 following cancer diagnosis, record the date as 00-00-0000. If the patient was diagnosed with COVID-19 after cancer diagnosis but there is no hospital admission due to COVID-19 specified in the medical record, code the date as 88-88-8888. If the patient had a hospital admission due COVID-19 after cancer diagnosis but the date of the hospital admission is not specified, code the date as 99-99-9999.

2.4. In **Item D**, record whether the medical record specifies an impact of COVID-19 on the definitive diagnosis. This is the medical procedure, usually involving examination of a biopsy, aspiration, or other tissue by a pathologist that confirms a diagnosis of cancer. Only record information specifically indicating effects of COVID-19 or coronavirus. If the medical record does not indicate an impact of COVID-19 on the definitive diagnosis, code Item D as "0". If the medical record indicates that the definitive diagnosis was delayed due to COVID-19, code Item D as "1". If the medical record indicates an impact on the definitive diagnosis due to COVID-19 other than delay, code Item D as "8" and enter the appropriate text in the "Other Specify" field.

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE (cont)

ITEM A-15

2.5. **Items E-H** collect information on impacts of COVID-19 on different aspects of cancer care specified in the medical record. Only record information specifically indicating effects of COVID or coronavirus.

2.6. In **Item E**, record whether the medical record specifies an impact of COVID-19 on the patient's first cancer surgery to the primary site. This can be potentially curative surgery or palliative surgery. If the medical record does not indicate an impact of COVID-19 on the first cancer surgery to the primary site, code Item E as "0". If the medical record indicates that the first cancer surgery to the primary site was delayed due to COVID-19, code Item E as "1". If the medical record indicates that the first cancer surgery to the primary site was altered other than a delay due to COVID-19 (e.g., change in the facility where the surgery was performed, change from inpatient to outpatient procedure, or change in the type of surgical procedure performed), code Item E as "2". If the medical record indicates that the first cancer surgery to the primary site was canceled by health care personnel (not by the patient) due to COVID-19, whether or not the surgery was subsequently rescheduled, code Item E as "3". If the medical record indicates that the patient refused the first cancer surgery to the primary site due to COVID-19, whether or not the surgery was subsequently rescheduled, code Item E as "4". If the medical record indicates some other impact on the patient's surgery due to COVID-19, code as "8" and enter the appropriate text in the "Other Specify" field. If the patient did not receive cancer surgery to the primary site for reasons other than COVID-19, for unknown/unspecified reasons, or surgery was not planned first course, code Item E as "9".

2.7. In **Item F**, record whether the medical record specifies an impact of COVID-19 on the patient's first course of radiation therapy to the primary site. This can be a potentially curative radiation therapy or palliative radiation therapy. If the medical record does not indicate an impact of COVID-19 on the first course of radiation therapy to the primary site, code Item F as "0". If the medical record indicates that the first course of radiation therapy to the primary site was delayed due to COVID-19, code Item F as` "1". If the medical record indicates that the first course of radiation therapy to the primary site was altered other than a delay due to COVID-19 (e.g., change in the facility where the radiation therapy was administered or change in the type, duration, or frequency of radiation therapy treatments), code Item F as "2". If the medical record indicates that the first course of radiation therapy to the primary site was canceled by health care personnel (not by the patient) due to COVID-19, whether or not the radiation therapy was subsequently rescheduled, code Item F as "3". If the medical record indicates that the patient refused first course of radiation therapy to the primary site due to COVID-19, whether or not the radiation

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE (cont)

ITEM A-15

therapy was subsequently rescheduled, code Item F as "4". If the medical record indicates some other impact on radiation due to COVID-19, code as "8" and enter the appropriate text in the "Other Specify" field. If the patient did not receive radiation therapy to the primary site for reasons other than COVID-19, for unknown/unspecified reasons, or radiation was not planned first course, code Item F as "9".

2.8. In **Item G**, record whether the medical record specifies an impact of COVID-19 on the patient's first course of systemic therapy. This can be a potentially curative systemic therapy or palliative systemic therapy. If the medical record does not indicate an impact of COVID-19 on the first course of systemic therapy, code Item G as "0". If the medical record indicates that the first course of systemic therapy was delayed due to COVID-19, code Item G as "1". If the medical record indicates that the first course of systemic therapy altered other than a delay due to COVID-19 (e.g., change in the facility where the systemic therapy was administered or change in the type, duration, or frequency of systemic therapy treatments, including a change from parenteral to oral systemic therapy), code Item G as "2". If the medical record indicates that the first course of systemic therapy was canceled by health care personnel (not by the patient) due to COVID-19, whether or not the systemic therapy was subsequently rescheduled, code Item G as "3". If the medical record indicates that the patient refused first course of systemic therapy due to COVID-19, whether or not the systemic therapy was subsequently rescheduled, code Item G as "4". If the medical record indicates some other impact on systemic therapy due to COVID-19, code as "8" and enter the appropriate text in the "Other Specify" field. If the patient did not receive systemic therapy for reasons other than COVID-19, for unknown/unspecified reasons, or systemic therapy was not planned first course, code Item G as "9".

2.9. In **Item H**, record whether the medical record specifies an impact of COVID-19 on palliative therapy. This can include pain management, rehabilitative services (e.g., physical therapy), or treatment of other systems associated with cancer or cancer treatment, as well as surgery, radiation therapy, or systemic therapy that is specifically designated as palliative. If the medical record does not indicate an impact of COVID-19 on the palliative therapy, code Item H as "0". If the medical record indicates that the palliative therapy was delayed due to COVID-19, code Item H as` "1". If the medical record indicates that the palliative therapy altered other than a delay due to COVID-19 (e.g., change in the facility where palliative therapy was administered or change in the type, duration, or frequency of palliative therapy treatments, including a change from in-person to virtual palliative therapy), code Item H as "2". If the medical record indicates that the palliative therapy was canceled by

IMPACT OF COVID-19 PANDEMIC ON CANCER CARE (cont)

ITEM A-15

health care personnel (not by the patient) due to COVID-19, whether or not palliative therapy was subsequently rescheduled, code Item H as "3". If the medical record indicates that the patient refused palliative therapy due to COVID-19, whether or not palliative therapy was subsequently rescheduled, code Item H as "4". If the medical record indicates some other impact on palliative therapy due to COVID-19, code as "8" and enter the appropriate text in the "Other Specify" field. If the patient did not receive palliative therapy for reasons other than COVID-19, for unknown/unspecified reasons, or palliative care was not planned first course, code Item H as "9".

IMPACT OF COVID-19 PANDEMIC ON FINANCES/INSURANCE

ITEM A-16

1. **Code**: 1 digit each

A. Impact of COVID-19 pandemic on patient's finances following cancer diagnosis

0 No impact of COVID-19 on patient's finances specified in medical record
1 Medical record specifies impact of COVID-19 on patient's finances

B. Impact of COVID-19 pandemic on patient's employment following cancer diagnosis

0 No impact of COVID-19 on patient's employment in medical record
1 Medical record specifies impact of COVID-19 on patient's employment

C. Impact of COVID-19 pandemic on patient's health insurance following cancer diagnosis

0 No impact of COVID-19 on patient's health insurances in medical record
1 Medical record specifies impact of COVID-19 on patient's health insurance

2. **Description**:

2.1. In **Items A-C**, record whether the medical record states there was any impact of the COVID-19 pandemic on the patient's finances, employment, or health insurance following cancer diagnosis. Only record information specifically indicating effects of COVID-19 or coronavirus.

2.2. To complete **Items A-C**, review the following sections of the medical record (when present): assessment and plan from oncology and palliative care clinician notes; oncology history from any clinician notes; palliative care notes; and chemotherapy and radiation therapy flow sheets.

2.3. In **Item A** include any mention of the impact of COVID-19 pandemic on patient's finances, including mention of financial hardship, debt, or loss of income following cancer diagnosis.

2.4. In **Item B** includes any mention of the impact of COVID-19 pandemic on patient's employment, including loss or change of job/employment following cancer diagnosis.

2.5. In **Item C** includes any mention of the impact of COVID-19 pandemic on patient's health insurance, including loss or change of health insurance following cancer diagnosis.

PALLIATIVE CARE

ITEM A-17

1. **Code**: 1 digit each

A. Receipt of palliative care after cancer diagnosis

0 No palliative care provided (Code date as 00-00-0000)
1 Surgery (which may involve a bypass procedure) to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
2 Radiation therapy to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
3 Chemotherapy, hormone therapy, or other systemic drugs to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
4 Patient received or was referred for pain management therapy with no other palliative care.
5 Any combination of codes 1, 2, and/or 3 without code 4.
6 Any combination of codes 1, 2, and/or 3 with code 4.
7 Palliative care was performed or referred, but no information on the type of procedure is available in the patient record.
8 Palliative care was provided that does not fit the descriptions for codes 1–6.
9 It is unknown if palliative care was performed or referred; not stated in patient record (Code date as 00-00-0000).

B. Date palliative care FIRST appears in medical record after cancer diagnosis

MM-DD-YYYY
00-00-0000 – Palliative care not listed in medical record or not given.
99-99-9999 – Date not available for first listing of palliative care in medical record

C. Receipt of counseling/mental health services after cancer diagnosis

0 No counseling/mental health services
1 Counseling/mental health services received, related to cancer diagnosis or symptoms
2 Counseling/mental health services received, unrelated to cancer diagnosis or symptoms
3 Counseling/mental health services received, unknown if related to cancer diagnosis or symptoms
9 Unknown if counseling/mental health services received

PALLIATIVE CARE (cont)

ITEM A-17

D. Date counseling/mental health care services FIRST appears in medical record after cancer diagnosis

MM-DD-YYYY

00-00-0000 – Counseling/mental health care services not listed in medical record or not given.

99-99-9999 – Date not available for first listing of counseling/mental health care services in medical record

E. Receipt of hospice services/admission after cancer diagnosis

0 No hospice services/admission

1 Hospice services/admission received

9 Unknown if hospice services/admission received

F. Date hospice services/admission FIRST appears in medical record after cancer diagnosis

MM-DD-YYYY

00-00-0000 – Hospice services/admission not listed in medical record

99-99-9999 – Date not available for first listing of hospice services/admission in medical record

2. **Description**:

2.1. In **Item A**, record the type of palliative care provided. Only services provided on or after the date of cancer diagnosis should be included, no matter how long after diagnosis. This does not need to be first course. This item is based on NAACCR Item #3280. For this item, only record treatment that is specified in the medical record as palliative, non-curative, or performed/administered to address symptoms or make the patient more comfortable.

2.2. Surgical procedures, radiation therapy, or systemic therapy provided to prolong the patient's life by controlling symptoms, to alleviate pain, or to make the patient comfortable should be coded as palliative care. Palliative care including surgery, radiation therapy, or systemic therapy can be received in addition to potentially curative surgery, radiation therapy, or systemic therapy. Palliative care should be coded in Item A regardless of whether or not curative therapy is also received.

PALLIATIVE CARE (cont)

ITEM A-17

2.3. Palliative care is not used to diagnose or stage the primary tumor or for potentially curative treatment.

2.4. Do **not** code routine **pain management** following surgery or other treatment; **DO** code first course pain management for persistent pain.

2.5. Do not code **hospice** care in Item A. Hospice care should be coded in **Item E**. If the patient did not receive any care listed as palliative (as specified in 2.1, above) but was admitted to hospice, code Item A as 0.

2.6. In **Item B**, specify the date that palliative care was first mentioned in the medical record. If palliative care was not mentioned or not received, (i.e., Item A is coded 0 or 9), then code as the date as 00-00-0000.

2.7. In **Item C**, record whether counseling, psychotherapy, or other mental health care services were received on or after the date of cancer diagnosis. This includes pastoral care, chaplains, or any type of therapist. If any of these services are specified as related to cancer diagnosis, cancer treatment, or symptoms resulting from the cancer diagnosis (e.g., anxiety or depression associated with cancer, cancer treatment, or effects of cancer or cancer treatment), code this as "1". If all counseling/mental health services are specified as related to causes other than cancer diagnosis, treatment, or associated symptoms (e.g., counseling for a mental health condition that was present prior to the cancer diagnosis), code this as "2". If it is unknown whether these services are or are not associated with cancer diagnosis, treatment, or associated symptoms, code this as "3". If it is unknown whether any counseling or mental health care services were received, code this as "9". Do not code receipt of counseling/mental health services if these services were discussed or recommended but the patient did not receive this care. If the patient was referred for counseling/mental health services but it is unknown whether these services were received, code Item C as 9.

2.8. In **Item D**, specify the date that counseling/mental health care services were first mentioned in the medical record, whether or not they were specifically related to cancer diagnosis, treatment, or symptoms. If counseling/mental health care services were not mentioned or not done, (i.e., coded 9 or 0 in Item C), then code as 00-00-0000.

PALLIATIVE CARE (cont)

ITEM A-17

2.9. In **Item E**, code whether the hospice services or admission to hospice were received on or after the date of cancer diagnosis. Hospice services can be inpatient or outpatient and does not need to be first course. Only record as hospice services/admission medical care that is specifically identified as hospice. Do not code other palliative or end-of-life care as hospice if it is not identified as hospice. Do not code receipt of hospice services/admission if hospice services/admission were discussed or recommended but the patient did not receive this care. If the patient was referred to hospice care but it is unknown whether hospice services/admission were received, code Item E as 9.

2.10. In **Item F**, specify the date that hospice services/admission were first mentioned in the medical record. If hospice services/admission were not mentioned or not done, (i.e., coded 9 or 0 in Item E), then code as 00-00-0000.

NEXTGEN SEQUENCING (NGS)

ITEM A-18

1. **Code**: 0 – Not performed
   1 – Performed, no positive findings
   2 – Performed, only positive finding is variants of unknown significance (VUS)
   3 – Performed, only positive finding is high tumor mutation burden (TMB) OR VUS and TMB in combination
   4 – Performed, only positive finding is variants of clinical significance OR variants of strong clinical significance OR VUS and variants of clinical significance/strong clinical significance in combination
   5 – Performed, positive finding is both high tumor mutation burden (TMB) AND variants of variants of clinical significance/strong clinical significance, with or without variants of unknown significance (VUS)
   6 – Performed, positive finding(s) other than variants of unknown significance (VUS), high tumor mutation burden (TMB), variants of clinical significance, or variants of strong clinical significance
   8 – Performed, findings unknown
   9 – Unknown if performed/no mention

2. **Description**:

   2.1. Next-generation sequencing (NGS) is a method used to determine a portion of the nucleotide sequence of a tumor's genome. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel. Examples of NGS tests include Foundation One, MSK IMPACT, Oncomine, Caris Molecular Intelligence, Trusight Oncology, Guandant360, and Myriad MYCHOICE. The type of NGS test used does not matter for this item, only whether or not NGS was performed.

   2.2. Code "0 – Not performed" if it was stated that the NGS test was not performed.

   2.3. Code "1 – Performed, no positive findings" when the NGS test was performed and there were not positive findings.

   2.4. Code "2 – Performed, only positive finding is variants of unknown significance (VUS)" if the NGS test was performed and the only positive findings were "variants of unknown significance" (VUS).

NEXTGEN SEQUENCING (NGS) (cont)

ITEM A-18

2.5. Code "3 – Performed, only positive finding is high tumor mutation burden (TMB) OR VUS and TMB in combination" if the NGS test was performed and the only positive findings were high tumor mutation burden (TMB) or **both** high tumor mutation burden (TMB) **and** variants of unknown significance (VUS).

2.6. Code "4 – Performed, only positive finding is variants of clinical significance OR variants of strong clinical significance OR VUS and variants of clinical significance/strong clinical significance in combination" if the NGS test was performed and the only positive findings were variants of clinical significance, variants of strong clinical significance or both variants of clinical significance/variants of strong clinical significance and variants of unknown significance (VUS).

2.7. Code "5 – Performed, positive finding is both high tumor mutation burden (TMB) AND variants of variants of clinical significance/strong clinical significance, with or without variants of unknown significance (VUS)" if the NGS test was performed and the only positive findings were both high tumor mutation burden (TMB) and variants of clinical significance or both high tumor mutation burden (TMB) and variants of strong clinical significance or the combination of high tumor mutation burden (TMB) and variants of clinical significance/variants of strong clinical significance and variants of unknown significance (VUS).

2.8. Code "6 – Performed, positive finding(s) other than variants of unknown significance (VUS) or high tumor mutation burden (TMB)" if the NGS test was performed and there were positive findings other than high tumor mutation burden (TMB) and/or variants of unknown significance (VUS). This may include high TMB and/or VUS findings in addition to other findings.

2.9. Code "8 – Performed, findings unknown" when the NGS test was performed and the findings are unknown or were not reported in the medical record.

2.10. Code "9 – Unknown if performed/no mention" if it is unknown whether the NGS test was performed, or there is no mention of it in the records.

GERMLINE MUTATIONS AND TESTING

ITEM A-19

1. **Code**:
   0 – Not performed
   1 – One or more of specified test performed, all positive
   2 – One or more of specified test performed, all negative
   3 – More than one of specified test performed, initially positive and subsequently negative
   4 – More than one of specified test performed, initially negative and subsequently positive
   5 – One or more of specified test performed, only positive finding is variants of unknown significance (VUS)
   8 – Test performed, result unknown
   9 – Unknown if performed/no mention

   Code separately for each of the following tests

   BRCA1
   BRCA2
   APC
   ATM
   CHEK2
   MLH1
   MSH2
   MSH6
   MUTYH
   PALB2
   PMS2

2. **Description**:

   2.1. Germline testing refers to molecular test of a patient's healthy cell, not tumor cells. It may be performed using a blood or saliva sample or a cheek swab.

   2.2. If the test was not performed, then code "0 – Test not performed".

   2.3. If a test was performed one or more times and all test results were positive, code that test as "1 – One or more of specified test performed, all positive".

   2.4. If a test was performed one or more times and all test results were negative, code that test as "2 – One or more of specified test performed, all negative".

GERMLINE MUTATIONS AND TESTING (continued)

ITEM A-19

2.5. If a test was performed more than one time and the test results were positive the first time but were negative for any subsequent test, code that test as "3 – More than one of specified test performed, initially positive and subsequently negative".

2.6. If a test was performed more than one time and the test results were negative the first time but were positive for any subsequent test, code that test as "4 – More than one of specified test performed, initially negative and subsequently positive".

2.7. If a test was performed one or more times and the only positive result was variants of unknown significance (VUS), then code "5". Use this code if there were negative findings in addition to positive VUS.

2.8. If there is mention of the test being performed in the record but no results, then code "8 – Test performed, results unknown".

2.9. If a patient received a panel of multiple tests (also called a "gene panel") and the specified mutation is listed as being part of the panel, assume that it was tested for. However, if the result is not listed, don't assume the test result was negative. If the specified test result is not listed, coded this as "8 –Test performed, result unknown".

2.10. If it is unknown if the test was performed, or there is no mention, then code "9 – Unknown/no mention if test performed".

SMOKING/TOBACCO USE

ITEM A-20

1. **Code**:

A. Number of cigarette packs per day

00.0 – Never smoked cigarettes
00.5 – Half a pack or less per day (≤0.5 ppd)
00.9 – More than half a pack to less than 1 pack per day (>0.5 to <1 ppd)
01.0 – 1 pack per day
02.0 – 2 packs per day
03.0 – 3 packs per day
...
...
55.5 – Light or occasional smoker
66.6 – Moderate smoker
77.7 – Heavy smoker
88.8 – Smoked, number of packs unknown
99.9 – Unknown, not stated whether patient smoked cigarettes

B. Non-cigarette tobacco use

0 – Never used non-cigarette tobacco products
1 – Reported use of e-cigarettes/vaping
2 – Reported use of cigars, pipes, and/or waterpipe tobacco/hookahs
3 – Reported use of smokeless tobacco products (chewing tobacco or snuff)
4 – Reported use of other non-cigarette tobacco products not listed above
5 – Reported use of multiple types of non-cigarette tobacco products
9 – Unknown, not stated whether patient ever used non-cigarette tobacco products

C. Number of years smoked or used other tobacco products

00 – Never smoked/used other tobacco products
01 – Smoked/used other tobacco products for one year
02 – Smoked/used other tobacco products for two years
...
...
88 – Smoked/used other tobacco products, number of years unknown
99 – Unknown, not stated whether patient smoked/used other tobacco products

SMOKING/TOBACCO USE (cont)

ITEM A-20

D. Pack Years

00 – Never smoked cigarettes and never used other tobacco products
01 – One pack-year history of cigarette smoking
02 – Two pack-year history of cigarette smoking
...
...
88 – Smoked cigarettes, pack years unknown
89 – >88 pack years
90 – Never smoked cigarettes but reported use of non-cigarette tobacco products (e-cigarettes, cigars, pipes, waterpipe, chewing tobacco, snuff, or other)
95 – Unknown if smoked cigarettes but reported use of non-cigarette tobacco products (e-cigarettes, cigars, pipes, waterpipe, chewing tobacco, snuff, or other)
99 – Unknown, not stated whether patient smoked cigarettes or used non-cigarette tobacco products

E. Smoking/Tobacco Use Status at Diagnosis (applies to cigarette smoking and use of non-cigarette tobacco products)

0 – Never smoked/used any non-cigarette tobacco products
1 – Current smoker/non-cigarette tobacco user
2 – Former smoker/ non-cigarette tobacco user
9 – Unknown if ever used any form of tobacco

2. **Description**:

2.1. This item is to be coded for any information known about the patient's smoking/tobacco use status. Code the number of packs per day, non-cigarette tobacco use, the number of years smoked and/or the pack years smoked as well as smoking/tobacco use status at diagnosis. If the patient never smoked cigarettes or used other forms of tobacco, code "00.0" in Packs Per Day; "0" in Non-cigarette tobacco use; code the Number of Years Smoked and Pack Years as "00"; and code Smoking Status at Diagnosis as "0". When multiple values for years, packs, or pack-years of smoking history are listed, record the lowest value presented.

2.2. If the patient smoked "half a pack or less per day," then code "00.5" in packs per day. If the record notes the patient smoked "less than a pack per day," then code "00.9" in packs per day.

SMOKING/TOBACCO USE (cont)

ITEM A-20

2.3. There are 20 cigarettes per pack. If the record states that the individual smoked 40 cigarettes per day for 10 years, then code 02.0 packs in the packs per day and 10 in number of years smoked; not 40.0 in the packs per day and 10 in the number of years smoked. Do not calculate pack years; code "88 – smoked pack years unknown" if number of pack-years smoked is not provided in the medical record. Record pack years only if it is given in the medical record.

2.4. If the patient is known to have smoked, but the number of packs is unknown, code "88.8- Smoked, number of packs unknown."

2.5. If the record does not give the number of cigarettes smoked, but instead states that the person was a heavy smoker, code "77.7 – Heavy smoker". A moderate smoker would be coded as "66.6" and a light smoker would be coded as "55.5".

2.6. If it is unclear or if it is not mentioned in the record whether the patient smoked, then code "99.9 - Unknown, not stated whether patient smoked" in packs, "99" in years and pack years, and "9" in Smoking Status at Diagnosis.

2.7. If the patient used non-cigarette tobacco product (either by themselves or in addition to cigarette smoking), code the appropriate information in Item B. If the patient used e-cigarettes vaping product, code as 1. If the patient used cigars, pipes, and/or waterpipes/hookahs, code as 2. If the patient used smokeless tobacco products including chewing tobacco or snuff, code as 3. If the patient used other non-cigarette tobacco products not listed, code as 4. If the patient used multiple types of non-cigarette tobacco products, code as 5. If it is unknown whether the patient used non-cigarette tobacco products, code as 9.

2.8. In **Item C**, "Number of years smoked or used other tobacco products", code as "00" if the patient never smoked or used other tobacco products. If the patient is known to have smoked cigarettes, code the number of years smoked if known; if the number of years he/she smoked is unknown, then code "88 - Smoked, number of years unknown". If the patient only used non-cigarette tobacco products, record the number of years non-cigarette tobacco products were used or code "88" if the number of years used is unknown. If the patient smoked cigarettes and used non-cigarette tobacco products, record only the number of years smoked cigarettes or code "88" if the number of years smoked cigarettes is unknown. If it is unknown whether the patient ever smoked/used non-cigarette tobacco products, code this item as "99".

2.9. If the record states, "The patient has been a heavy smoker for many years," without additional details, then code "77.7 – Heavy smoker" in packs (Item A), and "88 – Smoked cigarettes, number of years unknown" in years (Item C).

SMOKING/TOBACCO USE (cont)

ITEM A-20

2.10. If the record states number of pack years smoked, code this number in the "Pack Years" item (**Item D**). Code this item as "88 – Smoked cigarettes, number of pack years unknown" if the number of pack years is not specified. If the number of pack years smoked is 88 or more, code this item as "89 – >88 pack years." If the patient never smoked cigarettes but used other tobacco products, code Item D as "90". If it is unknown whether the patient ever smoked cigarettes but it is known that the patient used other tobacco products, code Item D as "95". If it is unknown whether the patient ever smoked cigarettes or used other tobacco products, code Item D as "99". If the patient never smoked or used other tobacco products, code Item D as "00".

2.11. Under "Smoking/Tobacco Use Status at Diagnosis" (**Item E**), code whether the patient never smoked cigarettes/used any non-cigarette tobacco products; was currently using cigarettes/ non-cigarette tobacco products at cancer diagnosis; or had previously used cigarettes/ non-cigarette tobacco products but was no longer doing so at cancer diagnosis. Code this item as "9" if it is unknown whether the patient ever smoked cigarettes or used non-cigarette tobacco products.

SECONDHAND SMOKE EXPOSURE

ITEM A-21

1. **Code**: 0 – Not exposed to secondhand smoke
   1 – Exposed to secondhand smoke
   9 – Unknown/not mentioned whether exposed to secondhand smoke

2. **Description**:

   2.1. Secondhand smoke exposure (also known as passive smoke exposure or passive smoking) is a risk for developing several serious diseases. Secondhand smoking occurs when one or more individuals in the patient's environment smokes. Whether or not the patient smokes, (s)he is forced to inhale the secondhand smoke when (s)he breathes. Patients may be exposed to secondhand smoke in their home, workplace, or in public places.

   2.2. Secondhand smoke exposure is coded separately from "active" smoking/tobacco use history (Item A-20). That is, even when a patient is listed as a current smoker, if they are also described as having secondhand smoke exposure, that should be recorded separately. However, do not code a current smoker/tobacco user as having secondhand smoke exposure only because they are exposed to their own smoking. Patients should be coded as having secondhand smoke exposure only if exposed to someone else's smoking, whether or not they themselves smoke.

   2.3. Code "0 – Not exposed to secondhand smoke" if the record indicates that the individual was not exposed to secondhand smoke.

   2.4. The patient would be considered "exposed" if (s)he reports working in an environment that permits smoking, such as a casino or bar that permits smoking. This should be coded as "1 – Exposed to secondhand smoke".

   2.5. A statement such as, "Husband/wife is a smoker" is **not** sufficient to indicate that the patient was exposed to secondhand smoke. Only if there is information stating that another individual smokes in the presence of the patient should this be coded as "1 – Exposed to secondhand smoke".

   2.6. If it is unclear or not mentioned whether the patient was exposed to secondhand smoke, then code "9 – Unknown, not mentioned whether exposed to secondhand smoke".

FAMILY HISTORY OF CANCER OF THE SAME SITE AND OF BREAST CANCER

ITEM A-22

1. **Code**:

A. Family history of cancer of the same site:

0 – No cancer of the same site reported among first-degree relatives

1 – Cancer of the same site reported among first-degree relatives

9 – Unknown/not mentioned whether cancer of the same site reported among first-degree relatives

B. Family history of breast cancer:

0 – No breast cancer reported among first-degree relatives

1 – Breast cancer reported among first-degree relatives

9 – Unknown/not mentioned whether breast cancer reported among first-degree relatives

2. **Description**:

2.1. A family history cancer of the same site (i.e., prostate cancer among individuals with prostate cancer or ovarian cancer among individuals with ovarian cancer) may be a risk factor for hereditary syndromes or genetic markers associated with increased risk of cancer. A family history of breast cancer among individuals diagnosed with prostate or ovarian cancer may also be a risk factor for hereditary syndromes or genetic markers associated with increased risk of cancer.

2.2. Collect separately for cancer of same site and for breast cancer. First-degree relatives are parents, siblings, or children. The diagnosis of the cancer reported among first-degree relatives can be **before or after** the cancer diagnosis for the individuals included in POC.

2.3. Code "0 – No family history" if the medical record indicates that there is no history of cancer of the same site/breast cancer among the patient's first-degree relatives.

2.4. Code "1 – Family history reported" if the medical record indicates that there is a history of cancer of the same site/breast among the patient's first-degree relatives.

2.5. Code "9 – Unknown/not mentioned" if the medical record indicates that it is unknown whether there is a history of cancer of the same site/breast cancer.

CO-MORBID CONDITIONS

ITEM C

1. **Code**: List all co-morbid conditions noted on the record at the time of initial diagnosis and during first course of treatment. These may be noted on the face sheet, discharge summary, nurse's notes, physician notes and/or the history and physical. **Please check the entire record.** Symptoms due to cancer or side-effects from cancer treatment are not considered co-morbid conditions. Comorbidities are conditions that were present **prior to the diagnosis** of cancer or are not related to cancer or cancer therapy.

2. **Description**:

   2.1. Co-morbid conditions: List all medical conditions, including histories of disease or health problems.

   2.2. If you run out of room in the co-morbid fields in POC SEER*Abs, list the others in the abstractor's comments.

   2.3. If the condition was reported as a history of, be certain that "HISTORY" is recorded with the condition.

   2.4. **This item is to record co-morbidities, <u>not side effects of treatment.</u>** A medical condition that is related to the cancer or cancer therapy should not be included.

   2.5. If there are no comorbidities, enter "**None**" in the first field only and **leave the remaining fields blank.** Do not enter "None" in any of the fields except the first comorbidity.

ABSTRACTOR ID

1. **Code**: Provide the assigned abstractor ID.

2. **Description**:

   2.1. Please code the 5-digit coder identification number provided to the individuals coding the abstract.

   2.2. If there are multiple abstractors, please include the identification of the individual consolidating the abstracts.

DATE ABSTRACTED

1. **Code**: mmddyyyy

2. **Description:**

   2.1. Code the month, day, and year that the final abstracting was completed. This might be the final abstracting of the hospital medical record, or it might be the date the physician verification form was completed.

   2.2. We are collecting treatment data, so it is important to know how long the patient was followed. For example, we are much less likely to find much treatment information for a patient whose DATE ABSTRACTED was 1 month following diagnosis. Compare this to an individual whose abstract was completed 18 months following diagnosis. This patient is much more likely to have been treated, perhaps with several regimens - e.g., chemotherapy and radiation.

   2.3. This is NOT the last date specified in the medical record. It is the date when the abstraction form was completed, which may involve review of medical records from multiple sources, or the date the physician verification form was received or the office visited.

POC DATA ACQUISITION MANUAL

SECTION IV

PROSTATE CANCER DATA SET

SECTION IV – PROSTATE DATA SET

CONTENTS

PSA FREE / TOTAL RATIO

ITEM B-1

1. Code

00.0 – Not performed
01.0-96.0 – Actual value
97.0 – Normal limits
98.0 – Elevated
99.9 – Unknown/No mention

2. Description

2.1. The ratio of free PSA in total PSA has been reported to improve the accuracy of the diagnosis of prostate cancer in men with a slightly elevated PSA.

2.2. Code the first ratio that is present in the medical records after the date of diagnosis.

2.3. Code the actual value of the PSA free/total (f/t) ratio, to the tenths place. It is expressed as a percent (e.g., 44%). Be certain that if the value is less than 10 it is reported with a leading zero (0). If no tenths place is given, code zero in the tenths position.

2.4. If no actual value is given, code whether the PSA f/t ratio was within normal limits, "97.0 – within normal limits" or if the PSA f/t is only reported as elevated, "code 98.0 – Elevated."

2.5. Code "99.9 – Unknown/no mention" if it is unknown whether the test was ordered or there is no mention.

PSA VALUE / DATE

ITEM B-2

1. Code 0000.0 – No PSA performed prior to biopsy or TURP
0000.1-8888.7 – Actual PSA value given in record
8888.8 – PSA performed, value unknown
9999.7 – Value greater than or equal to 8888.8
9999.9 – Unknown if PSA performed/no mention

MM-DD-YYYY
00-00-0000 – No PSA performed prior to biopsy or TURP

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the PSA value for the PSA closest to but preceding the biopsy or TURP (WHICHEVER IS FIRST) that confirmed the diagnosis of prostate cancer. Do not record values after biopsy, TURP or prostatectomy. Record the month, day and year the PSA was performed.

2.2. If no PSA was performed prior to the biopsy or TURP, code "0000.0" for the PSA value. Code the date as either "77-77-7777 – Refused", "95-95-9595 – Recommended, not performed" or "00-00-0000 – Not performed".

2.3. If no value can be found in the record, but it is known that PSA was done, code "8888.8" for the PSA value and code the date as "99-99-9999 – Date Unknown".

PSA VALUE / DATE (cont)

ITEM B-2

2.4. If it is unknown or cannot be determined from any of the medical records whether the patient had PSA performed, code “9999.9” for the PSA value. Code the date as “96-96-9696” if it is known that PSA testing was recommended but it is unknown if it was performed. Code the date as “97-97-9797” if it is unknown whether PSA was recommended and performed.

BIOPSY

ITEM B-3

1. Code

0 – Negative
1 – Positive
2 – Equivocal
7 – Done, Results unknown
8 – Not done
9 – Unknown if done

MM-DD-YYYY
00-00-0000 – No biopsy

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record findings from the BIOPSY performed which diagnosed the prostate cancer or which was closest to, but before the start of definitive therapy. Code "0 - Negative" if the BIOPSY was negative. Biopsy may be listed as a core biopsy or fine needle aspiration and may or may not be an ultrasound-guided procedure.

2.2. Code "1 – Positive" if on BIOPSY there was evidence of the disease.

2.3. Code "2 – Equivocal" if it cannot be determined whether there was evidence of disease. If the report uses words other than the ambiguous reportable terms listed in the SEER Program Coding and Staging Manual, 2007, code "2 - Equivocal."

2.4. Code "7 – Done, Results unknown" if the patient has had a BIOPSY, but the results are not known or cannot be found in the record.

BIOPSY (continued)

ITEM B-3

2.5. Code “8 – Not done” if the record states that no BIOPSY was performed.

2.6. Code “9 – Unknown if done” if the record does not give information about whether a BIOPSY was performed.

2.7. Record the month, day and year on which the biopsy was performed which confirmed the diagnosis of prostate cancer. Code “00-00-0000” if a BIOPSY was not performed.

2.8. Code “77-77-7777” if biopsy was recommended, but patient or family refused it.

2.9. Code “95-95-9595” if biopsy was recommended but it was not done.

2.10. Code “96-96-9696” if biopsy was recommended but it is unknown if it was done.

2.11. Code “97-97-9797 – Unknown” if it cannot be determined whether a BIOPSY was performed.

2.12. Code “99-99-9999 – BIOPSY performed, date unknown” if a BIOPSY was performed, but the date of the BIOPSY cannot be determined or estimated from the medical record. If the exact date of the biopsy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a biopsy two weeks ago, code date of biopsy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states the biopsy was performed “recently”, then estimate the month, but not the day. If the day, month or year is unknown, record 99 for that item.

NUMBER OF CORES TAKEN / CORES WITH CANCER

ITEM B-4

1. Code

Number of Cores taken
00 – no biopsy
01-96 – actual number of cores
97 – fine needle aspiration performed but no core biopsy/biopsies
98 – biopsy performed, number of cores taken unknown
99 – unknown if biopsy performed

Number of cores with Cancer
00 – no cores with cancer
01-96 – actual number of cores with cancer
97 – no biopsy
98 – cancer in cores, actual number of cores with cancer unknown
99 – unknown if core had cancer

2. Description

2.1. A prostate biopsy is usually performed at diagnosis to determine whether the man has prostate cancer. Normally 6-13 cores or samples are taken during the biopsy. The most common procedure is to access the prostate through the wall of the rectum as this provides reasonably easy access to the prostate gland. A spring loaded instrument removes a small piece of the prostate. Two other methods are to access the prostate gland through the urethra or to collect needle biopsy samples through the perineum.

2.2. If no needle biopsy was performed, code “00 – no biopsy.”

2.3. Code the actual number of cores taken AT DIAGNOSIS, 01-96. Code the total number of core samples.

2.4. If a fine needle aspiration was performed, code number of cores taken “97 – fine needle aspiration performed but no core biopsy/biopsies” and number of cores with cancer as “97 – no biopsy”

2.5. If a biopsy was performed, but the number of cores taken cannot be determined, code “98 – biopsy performed, number of cores taken unknown.”

2.6. If it is unknown whether a biopsy was performed, code number of cores taken as “99 – Unknown if biopsy performed.” If number of cores taken is coded as “99 – unknown,” then number of cores with cancer must also be coded as “99 – unknown”.

NUMBER OF CORES TAKEN / CORES WITH CANCER (continued)

ITEM B-4

2.7. Code the number of cores with cancer. If it is known that cores had cancer but is unknown how many, code “98 – cancer in cores, actual number of cores with cancer unknown.”

2.8. If the number of cores taken is coded “00 – no biopsy”, code number of cores with cancer as “97 – no biopsy”.

2.9. If the number of cores with cancer cannot be determined, code “99 – unknown if core had cancer”.

GLEASON GRADE (or PATTERN) / SCORE from BIOPSY

ITEM B-5

1. Code

Gleason Grade/Pattern
0 + 0 – No biopsy performed
6 + 6 – Biopsy negative
9 + 9 – Unknown/Not Reported
1 – 5 + 1 – 5 – Gleason Pattern or Grade range

Gleason Score
00 – No biopsy performed
66 – Negative biopsy
99 – Unknown/Not reported
02 - 10 – Gleason Score range

2. Description

2.1. Record the Gleason Grade, sometimes called Gleason Pattern, and the Gleason score as reported from the biopsy that confirmed the diagnosis of prostate cancer.

2.2. The Gleason Grade will be between 1 and 5. The Gleason score will be between 02 and 10.

2.3. Code "0 + 0" for the grade if no biopsy was performed and "00" for the score when no biopsy was performed.

2.4. A biopsy may have been done which was negative. Code "6 + 6 - negative" for grade and "66 - Negative biopsy" for score if the biopsy was normal and therefore would not have a grade assigned.

2.5. Code "9 + 9 - Unknown" if the Gleason Grade cannot be determined from the medical record. Code "99 - Unknown/Not reported" if the Gleason score cannot be determined from the medical record or if it is not reported. Do not add the Gleason Grade to obtain the score. Code it "99 - Unknown/Not reported" and in the analyses the computer can calculate the score.

2.6. Two grades are usually reported, one indicating the primary pattern and one from the secondary pattern. If more than two patterns are reported, code the two highest. If multiple Gleason grades are given and the Gleason Scores (sum of the two Gleason grades) are equal, then record the one that includes the highest grade (pattern). If the Gleason scores are not equal, then record the Gleason grades that produce the highest Gleason Score. Be certain that you are adding the two Gleason grades, not one Gleason grade and the Gleason Score.

GLEASON GRADE (or PATTERN)/ SCORE from BIOPSY (continued)

ITEM B-5

2.7. If there is only one number recorded and it does not specify grade or score, if the number is 6 or higher, it must be the Gleason Score. Record that number as the Gleason Score. If the number is 5 or less, but greater than 1, it may be the grade or the score. Since it is not possible to determine which it is, you must record unknown, "9 + 9" and "99." If the number is 1, it must be a Gleason grade, but the secondary pattern has not been recorded, therefore "99 - unknown" must be coded in the Gleason score.

2.8. Be careful not to confuse Gleason Grade and Gleason Score. If only the Gleason Grade is reported, then code Gleason Score as "99 - Unknown/Not reported". If only Gleason Score is given, then record grade as "9 + 9 – Unknown/not given".

2.9. If Item B-3 is coded "8 - biopsy not done", then Item B-5 must be coded "0+0 and 00" – no biopsy performed."

2.10. See the Site-Specific Data Item (SSDI) Manual for details on Gleason Grade (or pattern) and Gleason Score.

METHOD OF TUMOR DETECTION

ITEM B-6

1. Code

1 – Urinary signs/symptoms
2 – Non-urinary signs/symptoms
3 – Digital rectal (prostate) exam
4 – PSA screening
5 – Other, specify_____
9 – Unknown/Not specified

2. Description

2.1. Code "1 – Urinary signs/symptoms" when the patient reported signs/symptoms related to urination such as blood in urine or difficulty urinating that led to prostate cancer diagnosis. If there were multiple methods of tumor detection, lower codes have priority over higher codes. For example, if there were both urinary symptoms (code 1) and non-urinary symptoms (code 2), then use code "1-Urinary signs/symptoms".

2.2. Code "2 – Non-urinary signs/symptoms" when the patient reported signs/symptoms unrelated to urination that led to prostate cancer diagnosis.

2.3. Code "3 – Digital rectal (prostate) exam" when the patient's prostate abnormality was initially detected by a digital rectal examination (DRE) performed by his health care provider in the absence of any symptoms.

2.4. Code "4 – PSA Screening" when the tumor was first detected following a routine prostate specific antigen (PSA) screening lab test in the absence of any symptoms.

2.5. Code "5 – Other, specify" when the tumor was discovered by some other means. Specify the method of discovery. Symptoms should not be entered in Other, Specify.

2.6. Code "9 – Unknown/Not specified" when it cannot be determined from the records how the tumor was initially detected.

METASTASIS AT DIAGNOSIS

ITEM B-7

1. Code

0 – No evidence of metastasis at the site
1 – Yes, only pathologic confirmation of metastasis at the site
2 – Yes, only clinical confirmation of metastasis at the site
3 – Yes, both clinical and pathologic confirmation of metastasis at the site
9 – Unknown if metastasis at the site

Sites
Lung
Distant lymph node(s)
Bone
Liver
Other, specify (pathologic) _____
Other, specify (clinical) _____
Other, specify (clinical and pathologic) _____

2. Description

2.1. Refer to the 2021 SEER Program Coding and Staging Manual for complete details. Code information about metastasis identified at the time of diagnosis. Information about metastatic involvement may be clinical or pathologic. These codes are NOT the codes from the SEER Manual—the POC codes are expanded to capture clinical and pathologic information. This information should not be taken from autopsy records.

2.2. Code "0 – No" if there is no evidence of distant metastasis in the medical record or imaging reports.

2.3. Code "1 – Yes, only pathologic confirmation of metastasis at the site" when there is pathologic but no clinical evidence of distant metastasis. Pathologic confirmation requires a biopsy positive for cancer at the metastatic site and may be reported in a pathology report or surgical records.

2.4. Code "2 – Yes, only clinical confirmation of metastasis at the site" when there is clinical but no pathologic evidence of distant metastasis. Clinical confirmation can be derived from documentation in patient history or physical examination and imaging reports. However, imaging of distant organs is not required.

2.5. Code "3 – Yes, both clinical and pathologic confirmation of metastasis at the site" when there is clinical and pathologic confirmation of distant metastasis.

METASTASIS AT DIAGNOSIS

ITEM B-7

2.6. Code “9 - Unknown” if it is unknown whether there is metastasis at the site. If there is no information about whether the patient had any metastatic disease, all sites should be coded “9 – Unknown.”

EOD OF PRIMARY TUMOR

ITEM B-8

1. Code Prostate

2. Description

Code	Description	SS2018 T
000	In situ: noninvasive; intraepithelial	IS
100	Incidental histologic finding (for example, on TURP) in 5 percent or less of tissue resected (clinically inapparent)	L
110	Incidental histologic finding (for example, on TURP) in more than 5 percent of tissue resected (clinically inapparent)	L
120	Tumor identified by needle biopsy (clinically inapparent/not palpable) • Example - for elevated PSA	L
150	Incidental histologic finding (for example, on TURP), number of foci or percent of involved tissue not specified (clinically inapparent/not palpable)	L
200	Involves one-half of one side or less (clinically apparent/palpable)	L
210	More than one-half of one side but not both sides (clinically apparent/palpable)	L
220	Involves both lobes/sides (clinically apparent/palpable)	L
250	Confined to prostate, unknown lobe involvement (clinically apparent/palpable)	L
300	Localized, NOS Not known if clinically apparent or inapparent	L
350	Bladder neck, microscopic invasion Extraprostatic extension (beyond prostatic capsule), unilateral, bilateral, or NOS • WITHOUT invasion of the seminal vesicles Extension to periprostatic tissue WITHOUT invasion of the seminal vesicles	RE
400	Tumor invades seminal vesicle(s)	RE
500	Extraprostatic tumor that is not fixed • WITHOUT invasion of adjacent structures Periprostatic extension, NOS (unknown if seminal vesicle(s) involved) Extraprostatic extension, NOS (unknown if seminal vesicle(s) involved) Through capsule, NOS	RE

Code	Description	SS2018 T
600	Bladder neck Bladder, NOS External sphincter Extraprostatic urethra (membranous urethra) Fixation, NOS Levator muscles Rectovesical (Denonvillier's) fascia Rectum Skeletal muscle Ureter(s)	RE
700	Extension to or fixation to pelvic wall or pelvic bone "Frozen pelvis", NOS Further contiguous extension including • Other organs • Penis • Sigmoid colon • Soft tissue other than periprostatic	D
800	No evidence of primary tumor	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in medical record Death Certificate Only	U

Notes

Note 1: For this schema, the EOD Primary Tumor field captures a clinical extent of disease only. The guidelines for assigning Clinical Extension for AJCC and EOD are different. Per AJCC, a digital rectal exam (DRE) is required to assign a clinical T (cT). For EOD, a code can be assigned if there is no DRE information. (See Note 7).

Note 2: Information from radical prostatectomy and autopsy are recorded in EOD Prostate Pathologic Extension
Note: A simple prostatectomy (Surgery code 30) does not qualify for a radical prostatectomy. Results from a simple prostatectomy are recorded in EOD Primary Tumor

Note 3: Imaging is **not** used to determine the clinical extension. If a physician incorporates imaging findings into their evaluation (including the clinical T category), **do not** use this information.
- If it cannot be determined if the physician is using imaging, assume they are not and code the clinical extension based on the physician's statement

Note 4: Codes 100, 110, or 150 are used when there is a TURP only during the clinical workup

and there was no clinically apparent tumor (DRE negative or unknown) (See Note 6 if positive DRE).

- Code 150 if only a TURP is done, and the percentage of cells is not noted in the pathology report

Note 5: Code 120 when the tumor is clinically inapparent (DRE negative).

- Do not use this code when there is no information about the DRE results (see Note 7 for code 300).
- **Clinically** inapparent **tumors** are not palpable. Physician documentation of a DRE that does not mention a palpable "tumor", "mass", or "nodule" can be inferred as inapparent. This would include DRE findings of only benign prostate enlargement/hypertrophy
- Do not use ICD-10-CM code R97.20 (Elevated prostate specific antigen [PSA]) alone to code 120

Note 6: Codes 200-250 are for clinically apparent tumors (DRE positive).

- Clinically **apparent tumors** are palpable. If a clinician documents a "tumor", "mass", or "nodule" by physical examination, this can be inferred as apparent
- Do not infer inapparent or apparent tumor based on the registrar's interpretation of other terms

Note 7: Code 300 for localized cancers when the DRE result is not documented, or DRE not done and there is no clinical evidence of extraprostatic extension, or the physician incorporates imaging findings into their evaluation

- ***Examp***le 1: Patient with elevated PSA and positive needle core biopsy, but no documentation regarding tumor apparency (inapparent versus apparent), and there is no evidence of extraprostatic extension
- Example 2: Pathology report from a needle core biopsy done confirming cancer. No information on PSA, DRE or physician statement regarding clinical extension
- Example 3: Pathology report from a needle core biopsy done confirming cancer. No information on PSA, DRE or physician statement regarding clinical extension. Physician states imaging shows extraprostatic extension and assigns cT3a

Note 8: Codes 350-700 are for when there is positive extraprostatic extension, which can be determined by DRE, clinical exam, or needle core biopsy

- If a needle core biopsy confirms extraprostatic extension, that information can be used for EOD

Note 9: If there is no information from the DRE, or the terminology used is not documented in Note 5, but the physician assigns a clinical extent of disease, the registrar can use that.

- ***Exam***ple: DRE reveals prostate is "firm." Physician states the patient as a cT2a. The T2a can be used in the physician has documented this. Code 200
- Exce***ption:*** If the physician is clearly using imaging findings to determine clinical stage or extension of disease, do not use this information and code as 300 (Localized, NOS) (See Note 7)

Note 10: Involvement of the prostatic urethra does not alter the EOD code. Extraprostatic urethra involved is captured in code 600.

Note 11: "Frozen pelvis" is a clinical term which means tumor extends to pelvic sidewall(s). In the absence of a more detailed statement of involvement, assign a description of frozen pelvis to code 700.

Note 12: Code 800 when an incidental finding of prostate cancer is found during a prostatectomy

performed for other reasons (i.e., prostate cancer not suspected).

- ***Example 1:*** Cystoprostatectomy done for bladder cancer and prostate cancer found incidentally
- ***Example 2:*** Patient found to have prostate cancer during autopsy

Note 13: Code 999 when there is no documentation regarding a prostate evaluation (PSA, physical exam or physician's statement) prior to prostatectomy/autopsy.

- ***Example:*** Patient presents for prostatectomy for known prostate cancer. No information on clinical evaluation

TURP

ITEM B-9

1. Code

0 – Negative
1 – Positive
2 – Equivocal
7 – Done, Results unknown
8 – Not done
9 – Unknown if done

MM-DD-YYYY
00-00-0000 - No TURP performed

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record findings from the TURP (transurethral resection of the prostate) performed which diagnosed the prostate cancer or which was prior to the prostatectomy. Code "0 - Negative," if the TURP was negative.

2.2. Code "1 - Positive" if on TURP there was evidence of the cancer.

2.3. Code "2 - Equivocal" if it cannot be determined whether there was evidence of cancer. If the report uses words other than the ambiguous reportable terms listed in the SEER Program Coding and Staging Manual, 2021, code "2 - Equivocal."

2.4. Code "7 - Done, Results unknown" if the patient had a TURP, but the results are not known or cannot be found in the record.

2.5. Code "8 - Not done" if the record state that no TURP was performed.

TURP (continued)

ITEM B-9

2.6. Code “9 - Unknown if done” if the record does not give information about whether a TURP was performed.

2.7. Code the month, day and year of the TURP that confirmed the diagnosis of prostate cancer; or the TURP that followed a biopsy or aspiration that was positive for prostate cancer. Record the biopsy in Item B-3. Code “00-00-0000” if a TURP was not performed.

2.8. Code “77-77-7777” if TURP was recommended but patient or family refused it.

2.9. Code “96-96-9696” if a TURP was recommended but it is unknown if it was done.

2.10. Code “99-99-9999 - TURP performed, date unknown” if a TURP was performed, but the date of the TURP cannot be determined or estimated from the medical record. If the exact date of the TURP is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a TURP two weeks ago, code date of TURP as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states the TURP was performed “recently” estimate the month, but not the day. If the day, month or year is unknown, record “99” for that item.

2.11. Code “97-97-9797 - Unknown” if it cannot be determined whether a TURP was performed.

GLEASON GRADE (or PATTERN)/ SCORE from TURP

ITEM B-10

1. Code

Gleason Grade/Pattern
0 + 0 – No TURP performed
6 + 6 – TURP negative
9 + 9 – Unknown/Not Reported
1 – 5 + 1 - 5 – Gleason Pattern or Grade range

Gleason Score
00 – No TURP performed
66 – Negative TURP
99 – Unknown/Not reported
02 - 10 – Gleason Score range

2. Description

2.1. Record the Gleason Grade, sometimes called Gleason Pattern, and the Gleason score as reported from the TURP that confirmed the diagnosis of prostate cancer or followed the positive biopsy. The Gleason Grade will be between 1 and 5. The Gleason score will be between 2 and 10.

2.2. Code "0 + 0" for the grade if no TURP was performed, and "00" for the score when no TURP was performed.

2.3. A TURP may have been done which was negative. Code "6 + 6 - negative" for the grade and "66 - Negative TURP" for the score if the TURP was normal and therefore would not have a grade assigned.

2.4. Code "9 + 9 - Unknown" if the Gleason Grade cannot be determined from the medical record. Code "99 - Unknown/Not reported" if the Gleason score cannot be determined from the medical record or if it is not reported. Do not add the Gleason Grade to obtain the score. Code it "99 - Unknown/Not reported" and in the analyses the computer can calculate the score.

2.5. Two grades are usually reported, one indicating the primary pattern and one from the secondary pattern. If more than two patterns are reported, code the two highest. If multiple Gleason grades are given and the Gleason Scores (sum of the two Gleason grades) are equal record the one that includes the highest grade (pattern). If the Gleason scores are not equal record the Gleason grades that produce the highest Gleason Score.

GLEASON GRADE (or PATTERN)/ SCORE from TURP (continued)

ITEM B-10

2.6. If there is only one number recorded and it does not specify grade or score, if the number is 6 or higher, it must be the Gleason Score. Record that number as the Gleason Score. If the number is 5 or less, but greater than 1, it may be the grade or the score. Since it is not possible to determine which it is, you must record unknown, "9 + 9" and "99." If the number is 1, it must be a Gleason grade, but the secondary pattern has not been recorded, therefore "99-unknown" must be coded in the Gleason score.

2.7. Be careful not to confuse Gleason Grade and Gleason Score. If only the Gleason Grade is reported, then code Gleason Score as "99 - Unknown/Not reported. If only Gleason Score is given, then record grade as "9 + 9 – Unknown/not given".

2.8. If Item B-9 is coded "0 - TURP not performed", then Item B-10 must be coded "0+0 and 00" - TURP not performed."

2.9. See the Site-Specific Data Item (SSDI) Manual for details on Gleason Grade (or pattern) and Gleason Score.

DATE OF CRYOSURGERY

ITEM B-11

1. Code MM-DD-YYYY
00-00-0000 – No cryosurgery

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the month, day and year on which the cryosurgery was performed at any time following diagnosis.

2.2. Code “00-00-0000” if no cryosurgery was performed.

2.3. Code “77-77-7777” if the patient or patient’s guardian refused cryosurgery.

2.4. Code “96-96-9696” if cryosurgery was recommended, but unknown if given.

2.5. Code “97-97-9797” if it is unknown whether cryosurgery was performed.

2.6. Code “99-99-9999 - cryosurgery performed, date unknown” if cryosurgery was performed, but the date cannot be determined or estimated from the medical record. If the exact date of the cryosurgery is unknown, code an estimate. Coding the closest approximation is preferable to coding unknown. If it states the cryosurgery was performed “recently”, then estimate the month, but not the day. If the day, month or year is unknown, record 99 for that item.

TYPE/DATE OF PROSTATECTOMY

ITEM B-12

1. Code Type of prostatectomy

0 – No prostatectomy performed
1 – Open prostatectomy
2 – Robotic prostatectomy
3 – Laparoscopic prostatectomy
7 – Patient or guardian refused prostatectomy
8 – Prostatectomy performed, type unknown
9 – Unknown if prostatectomy performed

MM-DD-YYYY
00-00-0000 - NO PROSTATECTOMY

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the type of prostatectomy performed at any time following diagnosis. All types of prostatectomy should be recorded here.

2.2. Record the date the prostatectomy was performed.

2.3. Record “00-00-0000”, if no prostatectomy was performed.

2.4. Code “77-77-7777” if the patient or the patient’s guardian refused the prostatectomy.

2.5. Code “96-96-9696” if prostatectomy was recommended, but unknown if performed.

TYPE/DATE OF PROSTATECTOMY (continued)

ITEM B-12

2.6. Code “97-97-9797” if it is unknown whether a prostatectomy was recommended or performed.

2.7. Code “99-99-9999” if prostatectomy was performed but the date of the PROSTATECTOMY cannot be determined or estimated. If the exact date of the prostatectomy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a prostatectomy two weeks ago, code date of prostatectomy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states the prostatectomy was performed “recently”, then estimate the month, but not the day. Code “99” if either the month, day or year is unknown.

2.8. A TURP is NOT considered a prostatectomy.

GLEASON GRADE (or PATTERN)/ SCORE from PROSTATECTOMY

ITEM B-13

1. Code

Gleason Grade/Pattern
0 + 0 – No prostatectomy performed
6 + 6 – Prostatectomy negative
9 + 9 – Unknown/Not Reported
1 – 5 + 1 - 5 – Gleason Pattern or Grade range

Gleason Score
00 – No prostatectomy performed
66 – Negative prostatectomy
99 – Unknown/Not reported
02 - 10 – Gleason Score range

2. Description

2.1. Record the Gleason Grade, sometimes called Gleason Pattern, and the Gleason score as reported from the prostatectomy that confirmed the diagnosis of prostate cancer or followed the positive biopsy. The Gleason Grade will be between 1 and 5. The Gleason score will be between 2 and 10.

2.2. Code "0 + 0" for the grade if no prostatectomy was performed and "00" for the score when no prostatectomy was performed.

2.3. A prostatectomy may have been done which was negative. Code "6 + 6 - negative" for the grade and "66 – Negative prostatectomy" for the score if the prostatectomy was normal and therefore would not have a grade assigned.

2.4. Code "9 + 9 - Unknown" if the Gleason Grade cannot be determined from the medical record. Code "99 - Unknown/Not reported" if the Gleason score cannot be determined from the medical record or if it is not reported. Do not add the Gleason Grade to obtain the score. Code it "99 - Unknown/Not reported" and in the analyses the computer can calculate the score.

2.5. Two grades are usually reported, one indicating the primary pattern and one from the secondary pattern. If more than two patterns are reported, code the two highest. If multiple Gleason grades are given and the Gleason Scores (sum of the two Gleason grades) are equal, record the one that includes the highest grade (pattern). If the Gleason scores are not equal, record the Gleason grades that produce the highest Gleason Score.

GLEASON GRADE (or PATTERN)/ SCORE from PROSTATECTOMY (continued)

ITEM B-13

2.6. If there is only one number recorded and it does not indicate grade or score, if the number is 6 or higher, it must be the Gleason Score. Record that number as the Gleason Score. If the number is 5 or less, but greater than 1, it may be the grade or the score. Since it is not possible to determine which it is, you must record unknown, "9 + 9" and "99." If the number is 1, it must be a Gleason grade, but the secondary pattern has not been recorded, therefore "99," unknown must be coded in the Gleason score.

2.7. Be careful not to confuse Gleason Grade and Gleason Score. If only the Gleason Grade is reported, then code Gleason Score as "99 - Unknown/Not reported. If only Gleason Score is given, then record grade as "9 + 9 – Unknown/not given".

2.8. If Item B-12 is coded "00-00-0000 - prostatectomy not performed," Item B-13 must be coded "0+0 and 00" - prostatectomy not performed."

2.9. See the Site-Specific Data Item (SSDI) Manual for details on Gleason Grade (or pattern) and Gleason Score.

MARGINS / LOCATION

ITEM B-14

1. Code

Margins

0 – No prostatectomy performed
1 – Margins free of tumor per path report
2 – Pathology indicates tumor at margins of resection, or residual tumor in area of primary
3 – Margins not stated in path report--surgical report indicates no residual tumor
4 – Margins not stated in path report, surgical report indicates tumor at margins of resection, or residual tumor in area of primary
9 – Unknown, not stated

Location

0 – No prostatectomy performed/No positive margins
1 – Apical (apex)
2 – Lateral
3 – Bladder neck
4 – Posterior
5 – Apical + lateral and/or bladder neck and/or posterior
6 – Lateral + bladder neck and/or posterior
7 – Bladder neck + posterior
8 – Other (specify _____)
9 – Not stated/Unknown

2. Description

2.1. Code the status of pathological margins from the pathology report of the prostatectomy. This will not apply if there was no prostatectomy.

2.2. Code “0 - No prostatectomy performed” if no prostatectomy was performed.

2.3. Code “1 - Margins free of tumor” if there was no residual tumor following the prostatectomy per pathology report.

2.4. Code “2 - Tumor at margins” if there was residual tumor remaining after surgery per pathology report.

2.5. Code “3 - Margins not stated” if the pathology report does not state whether the margins are clear, but the surgical report indicates there is no residual tumor.

MARGINS / LOCATION (continued)

ITEM B-14

2.6. Code “4 –No mention in path report” if there is no mention of margins or residual tumor in path report but surgical report indicates tumor is present at margins of resection or there is residual tumor in the area of the primary.

2.7. Code “9 - Unknown, not stated” if the pathology report and the surgical report do not state whether there was tumor remaining.

2.8. The location of the positive surgical margin should be recorded from the pathology report. Record the location or specify if other than those listed above. If the location of the positive surgical margin is unknown or not stated, record “9 – unknown/not stated”. Select only one response for positive margin location, choosing the response that captures the information in the pathology report, if available.

ORCHIECTOMY

ITEM B-15

1. Code MM-DD-YYYY
00-00-0000 - No orchiectomy performed

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. An orchiectomy is performed to decrease the amount of male hormone circulating in the blood. This can slow the growth of the prostate cancer.

2.2. Record the month, day and year on which the orchiectomy was performed at any time following diagnosis.

2.3. Code “00-00-0000” if no orchiectomy was performed.

2.4. Code “77-77-7777” if the records indicate that an orchiectomy was recommended, but the patient or the patient’s guardian refused.

2.5. Code “96-96-9696” if the records indicate that the orchiectomy was recommended, but it is unclear whether the patient had it performed.

2.6. Code “97-97-9797” if it is unknown whether an orchiectomy was performed.

2.7. Code “99-99-9999” if the date of the orchiectomy cannot be determined or estimated. If the exact date of the orchiectomy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a orchiectomy two weeks ago, code date of orchiectomy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states the orchiectomy was performed “recently”, then estimate the month, but not the day. Code “99” if either the month, day or year is unknown.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-16
ITEM B-17

1. Code **B-16 – Number of positive regional lymph nodes**

00 – All examined nodes negative
01 – One positive node
02 – Two positive nodes
...
...
90 – 90 or more positive nodes
95 – Positive aspiration or core biopsy of lymph node(s) performed
97 – Positive nodes documented – number unspecified
98 – No nodes examined
99 – Unknown, not stated

B-17 – Number of regional lymph nodes examined

00 – No nodes examined (no nodal dissection performed)
01 – One node examined
02 – Two nodes examined
...
...
90 – 90 or more examined
95 – No regional nodes removed, but aspiration or core biopsy of regional nodes performed
96 – Regional lymph node removal documented as sampling and number of nodes unknown/not stated
97 – Regional lymph node removal documented as dissection and number of nodes unknown/not stated
98 – Regional lymph nodes surgically removed but number of nodes unknown/not stated and not documented as sampling or dissection; nodes examined but number unknown
99 – Unknown/not stated whether nodes examined

2. Description

2.1. For information on which nodes are considered regional, refer to the AJCC Staging Manual 8th Edition.

2.2. Record the number of regional nodes examined by a pathologist and found to contain metastasis. These should be coded based only on data from lymph nodes that are pathologically examined, not from lymph nodes that are clinically examined or examined using imaging procedures.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-16 & B-17

2.3. Code the number of regional lymph nodes positive in Item B-16 and the number of regional lymph nodes examined in Item B-17. Include all node dissections done during the first course of therapy.

2.4. If more than one dissection was done during the first course of treatment, code the total number of lymph nodes positive and examined.

2.5. If the number of nodes positive was 90 or greater, code Item B-16 as "90". If the number of nodes examined was 90 or greater, code Item B-17 as "90".

2.6. If lymph nodes were known to be positive, but the exact number positive is unknown, code Item B-16 as "97".

2.7. If lymph nodes were known to be positive, but the exact number positive is unknown and the exact number examined is unknown, code Item B-16 as "97" and Item B-17 as "96", "97", or "98".

2.8. If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code Item B-16 "00" and B-17 "96", "97" or "98".

2.9. If no regional node dissection was done or no regional lymph nodes were removed/examined, and there was no aspiration or biopsy, code Item B-16 "98" and B-17 "00".

2.10. If it is unknown or not stated whether any nodes were either positive or examined, then code "99" in Items B-16 and B-17.

2.11. If regional lymph nodes were aspirated and no further dissection/sampling was done, code Item B-16 either "00" for negative or "95" if positive and code Item B-17 as "95".

2.12. If both node aspiration and node dissection were performed, code results from the node dissection.

2.13. When there is a difference in the number of nodes positive and/or examined between the body of the pathology report and the final medical report, code the information from the final medical report.

SOMATIC (TUMOR CELL) MUTATIONS AND TESTING

ITEM B-18

1. Code

0 – Test not performed
1 – One or more of specified test performed, all positive
2 – One or more of specified test performed, all negative
3 – More than one of specified test performed, initially positive and subsequently negative
4 – More than one of specified test performed, initially negative and subsequently positive
5 – One or more of specified test performed, only positive finding is variants of unknown significance (VUS)
8 – Test performed, result unknown
9 – Unknown if test performed/no mention

Code separately for each of the following tests
MSI/Microsatellite instability (MSI-H)
MMR deficiency/Mismatch repair deficiency
BRCA1
BRCA2
ATM
PALB2
FANCA
RAD51D
CHEK2
CDK12
Circulating tumor DNA (ctDNA)

2. Description

2.1. Molecular marker or mutations status information can come from either the primary tumor or from metastases; if tests are performed on either the primary tumor or a metastasis, the specified marker/mutation should be coded using the values indicated.

2.2. If the test was not performed, then code “0 – Test not performed”

2.3. If a test was performed one or more times and all test results were positive, code that test as “1 – One or more of specified test performed, all positive”.

2.4. If a test was performed one or more times and all test results were negative, code that test as “2 – One or more of specified test performed, all negative”.

SOMATIC (TUMOR CELL) MUTATIONS AND TESTING (continued)

ITEM B-18

2.5. If a test was performed more than one time and the test results were positive the first time but were negative for any subsequent test, code that test as "3 – More than one of specified test performed, initially positive and subsequently negative".

2.6. If a test was performed more than one time and the test results were negative the first time but were positive for any subsequent test, code that test as "4 – More than one of specified test performed, initially negative and subsequently positive".

2.7. If a test was performed one or more times and the only positive result was variants of unknown significance (VUS), then code "5". Use this code if there were negative findings in addition to positive VUS.

2.8. If there is mention of the test being performed in the record but no results, then code "8 – Test performed, results unknown".

2.9. If a patient received a panel of multiple tests (also called a "gene panel") and the specified mutation is listed as being part of the panel, assume that it was tested for. However, if the result is not listed, don't assume the test result was negative. If the specified test result is not listed, coded this as "8 – One or more test performed, result unknown".

2.10. If there is no mention of the test in the records and no indication whether or not the test was performed, then code "9 – Unknown if test performed/no mention".

EXTERNAL RADIATION

ITEM B-19

1. Code

0 – No external radiation given
1 – EB, NOS
2 – IMRT
3 – IGRT
4 – 3D – Conformal
5 – 4D
6 – Other (specify) _____
7 – Radiation given, unknown if external or interstitial
8 – External radiation given, type unknown
9 – Unknown if given/no mention

2. Description

2.1. Radiation therapy is often given to patients with prostate cancer. The standard external beam radiation (EB) is the most common. However, newer treatments are increasing.

2.2. Code the type of radiation given for the treatment of prostate cancer (i.e., only to the primary site). This may be for either first line therapy or subsequent therapy. Do not code radiation administered to treat metastasis. Do not code radiopharmaceuticals that are administered as systemic therapy. Systemic infusion of radiation therapy should be coded in the Systemic Agents Item. Do not code radiation therapy provided specifically as part of palliative care; this should be included as part of the palliative care item (A-17).

2.3. If more than one type of radiation therapy is provided, code the dominant modality.

2.4. Intensity-modulated radiation therapy (IMRT) is an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. The radiation dose is designed to conform to the three-dimensional (3-D) shape of the tumor by modulating—or controlling—the intensity of the radiation beam to focus a higher radiation dose to the tumor while minimizing radiation exposure to surrounding normal tissues. Code “2 – IMRT” if the patient receives intensity-modulated radiation therapy.

EXTERNAL RADIATION (continued)

ITEM B-19

2.5. Radiation oncologists use image-guided radiation therapy, or IGRT, to help better deliver radiation since tumors can move between treatments due to differences in organ filling or movements while breathing. IGRT involves conformal radiation treatment guided by imaging, such as CT, ultrasound or X-rays, taken in the treatment room just before the patient is given the radiation treatment. All patients first undergo a CT scan as part of the planning process. The imaging information from the CT scan is then transmitted to a computer in the treatment room to allow doctors to compare the earlier image with the images taken just before treatment. During IGRT, doctors compare these images to see if the treatment needs to be adjusted. This allows doctors to better target the cancer while avoiding nearby healthy tissue. In some cases, doctors will implant a tiny marker in or near the tumor to pinpoint it for IGRT. Code "3 – IGRT" if patient receives image-guided radiation therapy.

2.6. **Three-Dimensional Conformal Radiation Therapy (3D-CRT)**
Tumors are not regular — they come in different shapes and sizes. Three-dimensional conformal radiation therapy, or 3D-CRT, uses computers and special imaging techniques to show the size, shape and location of the tumor. Computer assisted tomography (CT or CAT scans), magnetic resonance imaging (MR or MRI scans) and/or positron emission tomography (PET scans) are used to create detailed, three-dimensional representations of the tumor and surrounding organs. The radiation oncologist can then precisely tailor the radiation beams to the size and shape of the tumor with multileaf collimators or custom fabricated field shaping blocks. Because the radiation beams are very precisely directed, nearby normal tissue receives less radiation and is able to heal quickly. Code "4 – 3D - Conformal" if patient receives 3D conformal radiation therapy.

2.7. 4-D radiation therapy also takes into account the movement of the prostate gland. This is a relatively new technique and requires CT scans for the planning of the therapy. 4-D radiation therapy is synchronized with prostate gland motion and therefore delivers a dose more exactly to the tumor. Code "5 – 4D" if patient receives 4D radiation therapy.

2.8. Code "0 – No external radiation given" when external radiation was not given, including when it was refused.

2.9. Code "6 – Other" if the patient had another type of radiation therapy. Specify the type of therapy the patient received.

2.10. Code "7 – Radiation given, unknown if external or interstitial" when it is known that radiation was given, but it is unknown whether it was external or interstitial.

EXTERNAL RADIATION (cont)

ITEM B-19

2.11. Code “8 – External radiation given, type unknown” if external radiation was given but the type is unknown.

2.12. Code "9 – Unknown if given/no mention" if it cannot be determined whether external radiation was given, even if it was recommended.

INTERSTITIAL RADIATION

ITEM B-20

1. Code

0 – No interstitial radiation given
1 – Low dose rate implants, including seed implants
2 – High dose rate (HDR) implants
6 – Other, specify _____
7 – Radiation given, unknown if external or interstitial
8 – Interstitial radiation given, type unknown
9 – Unknown if given/no mention

2. Description

2.1. Interstitial radiation, also called brachytherapy, involves the actual placement of radioactive material into the prostate gland. The goal is to give a high dose of radiation to the cancer but limit the radiation to the surrounding structures. Do not code radiopharmaceuticals that are administered as systemic therapy in this Item. Systemic infusion of radiation therapy should be coded in the Systemic Agents Item.

2.2. The older type of interstitial radiotherapy, seed implantation, involves placing tiny low-dose rate implants into the prostate. These contain the radioactive material, are much smaller than grains of rice and are left permanently implanted in the prostate. The dose of radiation decreases over several days or weeks. This type of interstitial radiotherapy requires that the patient is anesthetized for placement of the seeds.

2.3. High dose implants (also called high-dose rate or HDR) stay in place for a few minutes at a time and then are taken out. The patient may be hospitalized for these treatments or may come in daily.

2.4. Code “0 – No interstitial radiation given” when interstitial radiation was not given, including when it was refused.

2.5. Code “7 – Radiation given, unknown if external or interstitial” when it is known that radiation was given, but it is unknown whether it was external or interstitial.

2.6. If interstitial radiation was given but the specific type is unknown, code “8 – Interstitial radiation given, type unknown”.

2.7. Code "9 – Unknown if given/no mention" if it cannot be determined whether radiation was given, even if it was recommended.

TOTAL RADIATION DOSE / UNITS

ITEM B-21

1. Code

Dose or Number of Injections/Infusions
0000.0 – No radiation given
0001.0-9996.0 – Dose or number of injections/infusions
9997.0 – Patient or guardian refused radiation
9998.0 – Radiation recommended, unknown if given
9998.8 – Radiation given, dose unknown/cannot be determined
9999.1 – Radiation given, modality unknown
9999.9 – Unknown if radiation given

Unit of Measure
0 – No radiation given
1 – cGy
2 – Gy
3 – Number of injections/infusions (radioisotopes only)
4 – Other (specify) _____
8 – Radiation given, modality unknown
9 – Unknown if given/no mention/unknown dose

2. Description

2.1. This item captures total dose of radiation received **to the pelvic area only** for ***one*** type of radiation modality, in the following priority order:

- External radiation
- Brachytherapy
- Radioisotope injection/infusion

Examples:

- Patient received external radiation and radioisotopes. Code the dose from the external radiation and ignore the radioisotopes.
- Patient received brachytherapy and radioisotopes. Code the dose from the brachytherapy and ignore the radioisotopes.
- Patient received only radioisotopes. Code the number of injections/infusions.

2.2. Code the total dose received for the highest priority radiation modality, even if the dose is unknown.

TOTAL RADIATION DOSE / UNITS

ITEM B-21 (cont)

2.3. This information will be found in the radiation therapy record. The report usually contains a summary following the final radiation treatment. The summary lists all doses of radiation given to the patient over the course of therapy and includes both external and interstitial radiation. For example, the summary might say:

	Radiation	– Total pelvic radiation	7900.0 cGy
or	Radiation	– Whole pelvic radiation	8,400.0 cGy

2.4. Extend to one decimal place if needed (nnnn.n). For radioisotope injections/infusions, code the number of injections/infusions in the dose field. For example, 5 doses would be coded as 0005.0.

2.5. If both Item B-19 and B-20 are coded "9 – Unknown if radiation therapy given/no mention", Item B-21 must be coded "9999.9" as well.

2.6. If the total pelvic dose for the highest priority modality is not recorded or cannot be determined from the radiation therapy record, but it is clear that modality of radiation therapy was given, code "9998.8 – radiation given, dose unknown/cannot be determined" and code the Units as "9".

2.7. In the units field, code "1 – cGy" if the unit of measure was centigray (cGy). Code "2 – Gy" if the unit of measure was gray (Gy). Code "4 – Number of injections/infusions" if the modality recorded is radioisotopes. Code "3 – Other" if the unit of measure was other than cGy, Gy, or number of injections/infusions, and record the specific the unit of measure.

2.8. If number of radioisotopes is recorded in Item B21, then Item B19 (External Radiation) should be coded as "0 – No external radiation given" or "9 – Unknown if given/no mention."

2.9. If it is known that radiation was given but the modality is unknown, then code Dose as "9999.1" and Units as "8".

DATE RADIATION BEGAN

ITEM B-22

1. Code MM-DD-YYYY
00-00-0000 - No radiation given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the month, day and year on which the radiation to the PRIMARY SITE (i.e., the prostate) was begun any time after diagnosis. This could be external or interstitial radiation therapy.

2.2. Code "00-00-0000" if no radiation was performed.

2.3. Code "77-77-7777" if the records indicate that radiation was recommended, but the patient or patient's guardian refused.

2.4. Code "96-96-9696" if the records indicate that radiation was recommended, but it is unclear whether the patient had radiation.

2.5. Code "97-97-9797" if it is unknown whether radiation was performed.

2.6. Code "99-99-9999" if the month, day and year the radiation began cannot be determined. If the exact date is unknown, code an estimate (e.g., if in history and physical, the physician states the patient started radiation therapy two weeks ago, code date of start of radiation therapy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states radiation therapy started "recently", then estimate the month, but not the day. Code "99" if either the month, day or year is unknown.

DATE RADIATION ENDED AND RADIATION COMPLETION STATUS

ITEM B-23

1. Code MM-DD-YYYY
00-00-0000 - No radiation given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

Radiation course completion status

0 – No, not completed
1 – Yes, completed
2 – No radiation given to primary site
3 – Radiation given, unknown if completed
9 – Unknown whether radiation was given

2. Description

2.1. Record the month, day and year on which the radiation to the PRIMARY SITE (the prostate) ended. This could be external or interstitial radiation therapy.

2.2. Code “00-00-0000" if no radiation was performed.

2.3. Code “77-77-7777” if the records indicate that radiation was recommended, but the patient or guardian refused.

2.4. Code “96-96-9696” if the records indicate that radiation was recommended, but it is unclear whether the patient had radiation.

2.5. Code “97-97-9797” if it is unknown whether radiation was performed.

DATE RADIATION ENDED AND RADIATION COMPLETION STATUS (continued)

ITEM B-23

2.6. Code "99-99-9999" if the month, day and year the radiation ended cannot be determined. If the exact date is unknown, code an estimate (e.g., if in history and physical, the physician states the patient completed radiation therapy two weeks ago, code date of completion of radiation therapy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states the radiation therapy ended/was completed "recently", then estimate the month, but not the day. Code "99" if either the month, day or year is unknown.

2.7. Code whether the full course of radiation was completed (Code "1– Yes, completed") or if the patient received less than a full course of radiation (Code "0 – No, not completed").

2.8. If the patient did not receive radiation to the primary site, code date as "00-00-0000" and completion as "2 – No radiation given to primary site."

2.9. If the patient did receive radiation to the primary site, but it is unknown if the radiation therapy was completed, code date as specified above and completion as "3 – Radiation given, unknown if completed."

2.10. If it is unknown whether radiation to the primary site was given, then code completion as "9 - unknown."

ACTIVE SURVEILLANCE / WATCHFUL WAITING / EXPECTANT MANAGEMENT

ITEM B-24

1. Code

A. Did patient receive active surveillance/watchful waiting/expectant management?

0 – No
1 – Yes, medical record specifies patient received active surveillance
2 – Yes, medical record specifies patient received watchful waiting and/or expectant management but does not specify/list active surveillance
7 – Recommended, patient or guardian refused
8 – Recommended, unknown if treated
9 – Unknown

B. As part of active surveillance/watchful waiting/expectant management, how frequently was PSA monitoring performed?

0 – Every 3-4 months
1 – Every 6 months
2 – Every 12 months
3 – Every 3-4 months for the first year following diagnosis, then less frequently
4 – Other (specify) _____
8 – Active surveillance/watchful waiting/expectant management was not first line treatment OR unknown if first line treatment
9 – Active surveillance/watchful waiting/expectant management was first line treatment but frequency of PSA monitoring is unknown

C. As part of active surveillance/watchful waiting/expectant management, when was the patient's first repeat biopsy (i.e., first biopsy after diagnosis)?

0 – At 6 months
1 – At 12 months
2 – At 18 months
3 – Repeat biopsy to be performed only if clinical or imaging changes noted
4 – Other (specify) _____
8 – Active surveillance/watchful waiting/expectant management was not first line treatment OR unknown if first line treatment
9 – Active surveillance/watchful waiting/expectant management was first line treatment but time to first repeat biopsy is unknown

ACTIVE SURVEILLANCE/WATCHFUL WAITING/EXPECTANT MANAGEMENT (cont)

ITEM B-24

D. As part of active surveillance/watchful waiting/expectant management, when was the patient's first repeat prostate imaging (e.g., MRI, PET, ultrasound) performed?

0 – At 3 months
1 – At 6 months
2 – At 12 months
3 – At 18 months
4 – At 24 months
5 – Repeat imaging to be performed only if clinical changes noted
6 – Other (specify) _____
8 – Active surveillance/watchful waiting/expectant management not first line treatment OR unknown if first line treatment
9 – Active surveillance/watchful waiting/expectant management was first line treatment but time to first repeat imaging is unknown

E. Did the patient stop receiving active surveillance/watchful waiting/expectant management (i.e., received surgery, radiation therapy, hormonal therapy, or other systemic therapy)?

0 – No
1 – Yes
8 – AS/WW/EM not first line treatment OR unknown if first line treatment
9 – Unknown if patient stopped receiving AS/WW/EM

F. WHY did the patient stop receiving active surveillance/watchful waiting/expectant management (select all that apply)?

a – Change on repeat biopsy
b – Increased tumor volume
c – Single rise in PSA level
d – Two of more consecutive rises in PSA level
e – Change in PSA velocity / PSA doubling time
f – Change in PSA density
g – Change in imaging findings
h – Patient request/preference for different treatment
i – Other (specify) _____
j – Active surveillance/watchful waiting/expectant management not first line treatment OR unknown if first line treatment
k – AS/WW/EM was first line treatment and patient did not stop receiving this treatment
l – AS/WW/EM was first line treatment but unknown if patient stopped receiving this treatment

ACTIVE SURVEILLANCE/WATCHFUL WAITING/EXPECTANT MANAGEMENT (cont)

ITEM B-24

2. Description

2.1. Prostate cancer can grow very slowly in some cases. Men, especially older men, may die of other diseases before they die of their prostate cancer. Sometimes physicians recommend waiting until the prostate cancer becomes a problem before they take any action. This is referred to as "active surveillance." It was previously called "watchful waiting" or "expectant management." PSA tests are usually performed every 2 to 4 months during watchful waiting. Sometimes the physicians will abbreviate these to AS or WW. Because the physicians use these terms interchangeably, we cannot separate AS which is sometimes associated with curative intent from WW which is sometimes associated with palliative care.

2.2. For Item A, Code "0 – No" if active surveillance, watchful waiting, or expectant management was not used as the first line therapy. Use this code if surgery, radiation, or hormonal therapy was used as a first course of therapy.

2.3. Code Item A as "1 – Yes, medical record specifies patient received active surveillance" if active surveillance is specified as the first line of therapy, even if at some later point active treatment (surgery, radiation therapy, hormonal therapy, or other systemic therapy) is initiated.

2.4. Code Item A as "2 – Yes, medical record specifies patient received watchful waiting and/or expectant management but does not specify/list active surveillance" if the patient received watchful waiting or expectant management as the first line of therapy, and "active surveillance" is not mentioned in the medical record. If the physician states that s/he will observe/watch the disease only, code this item "2" even if at some later point active treatment (surgery, radiation therapy, hormonal therapy, or other systemic therapy) is initiated.

2.5. For active surveillance and watchful waiting/expectant management, the physician may recommend regular or routine PSA every 2 to 4 months, or may recommend another biopsy at some interval of time; this can be part of active surveillance and watchful waiting/expectant management, but is not required to be stated in the medical record to define this type of care. Code "1" or "2" only if the physician recommended active surveillance or watchful waiting/expectant management.

2.6. DO NOT code the patient as having received active surveillance or watchful waiting/expectant management if the patient refused or delayed treatment.

ACTIVE SURVEILLANCE/WATCHFUL WAITING/EXPECTANT MANAGEMENT (cont)

ITEM B-24

2.7. If the record indicates that the physician recommended active surveillance or watchful waiting/expectant management, but the patient or guardian refused, code Item A as "7 – Recommended, patient or guardian refused." The patient may feel he wants a more active treatment. He may want the cancer "removed."

2.8. Code Item A as "8 – Recommended, unknown if treated" if the record indicates that active surveillance, watchful waiting, or expectant management was recommended but it cannot be determined from the medical records whether the patient actually had this mode of treatment or if he had active treatment as first line therapy.

2.9. Code Item A as "9 – Unknown" if it cannot be determined whether active surveillance, watchful waiting, or expectant management was recommended or followed as first line treatment.

2.10. For Item B, code how frequently PSA testing was performed during active surveillance/watchful waiting/expectant management. If none of the response options correspond to the reported pattern of PSA testing, select the option that is closest to the testing pattern or code as "4 – Other" and specify the PSA testing pattern.

2.11. For Item C, code when the first biopsy during active surveillance/watchful waiting/expectant management was performed. This should not be a biopsy performed during diagnosis. If none of the response options correspond to the time interval of the repeat biopsy, select the option that is closest or code as "4 – Other".

2.12. For Item D, code when the first prostate imaging (MRI, PET, ultrasound) during active surveillance/watchful waiting/expectant management was performed. This should not be an imaging performed during diagnosis. If none of the response options correspond to the time interval of imaging, please select the option that is closest or code as "6 – Other".

2.13. For Item E, code whether the patient stopped receiving active surveillance/watchful waiting/expectant management during the time period included in available medical records. This could correspond to the patient receiving surgery, radiation therapy, or systemic therapy.

2.14. For Item F, if the patient stopped receiving active surveillance/watchful waiting/expectant management during the time period included in available medical records (Item E coded as "1 - Yes"), code reasons stated in the medical record why active surveillance/watchful waiting/expectant management was stopped. Please code all reasons that are mentioned/listed as either 0 = not a reason stopped/not mentioned or 1 = listed as a reason for stopping.

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS

ITEM B-25

1. Code

i) Metastasis or local recurrence after diagnosis

0 – Patient had metastatic disease at diagnosis
1 – No evidence of metastasis or local recurrence after diagnosis
2 – Yes, metastasis at a distant site identified after diagnosis
3 – Yes, local recurrence at primary tumor site identified after diagnosis
4 – Yes, both metastasis and local recurrence identified after diagnosis
9 – Unknown if metastasis or local recurrence after diagnosis

ii) Date first metastasis or local recurrence identified after diagnosis

MM-DD-YYYY
00-00-0000 – No evidence of metastasis or local recurrence; Patient had metastatic disease at diagnosis; or Unknown if metastasis or local recurrence after diagnosis

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. This item collects information on whether a cancer metastasis or local recurrence is identified after the initial tumor diagnostic work-up. Metastasis refers to the presence of the same cancer at a site distant from the primary tumor. Local recurrence refers to the presence of the same cancer at the primary tumor site after the primary tumor has been removed. If the primary tumor is not removed, there cannot be a local recurrence.

2.2. For item (i), Code "0 - Patient had metastatic disease at diagnosis" if at initial diagnosis the patient was diagnosed with metastatic disease (M-stage M1 or coded as "Yes" in Item B-8, "METASTASIS AT DIAGNOSIS").

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS (continued)

ITEM B-25

2.3. Code "1 – No" if there is no evidence of metastasis or local recurrence in the medical record or imaging reports after the initial tumor diagnosis work-up. The initial tumor diagnostic work-up is not just the initial biopsy but also includes subsequent imaging studies to determine the initial stage of the patient's cancer. This option should be selected only if the patient did not have metastatic disease at diagnosis. If the patient had metastatic disease at diagnosis (M-stage M1 or coded as "Yes" in Item B-8), instead use code "0 - Patient had metastatic disease at diagnosis".

2.4. Code "2 – Yes, metastasis at a distant site identified after diagnosis" when there is clinical or pathologic evidence of distant metastasis after diagnosis for patients who did not have an initial diagnosis of metastatic cancer.

2.5. Code "3 – Yes, local recurrence at primary tumor site identified after diagnosis" when there was surgery to completely remove the primary tumor and after the surgery there is clinical or pathologic evidence of a new cancer of the same type at the site of the primary tumor.

2.6. Code "4 – Yes, both metastasis and local recurrence identified after diagnosis" when there is clinical and pathologic evidence of distant metastasis after diagnosis AND clinical or pathologic evidence of local recurrence at the primary tumor site.

2.7. Code "9 - Unknown" if it is unknown whether there is metastasis or local recurrence after diagnosis.

2.8. For item (ii), code the first date that the metastasis or local recurrence after initial diagnosis listed in the medical record. If the patient had metastatic disease at diagnosis (item (i) coded "0"), no evidence of metastasis or local recurrence (item (i) coded "1"), or unknown whether there is metastasis or local recurrence after diagnosis (item (i) coded "9"), code item (ii) "00-00-0000".

SYSTEMIC THERAPY AGENTS

ITEM B-26 THROUGH B-56

1. Code MM-DD-YYYY
00-00-0000 - No systemic therapy given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not given
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

B-26 Abiraterone acetate (Zytiga, Yonsa)

B-27 Combination niraparib plus abiraterone (Akeega)

B-28 Aminoglutethimide (Cytadren)

B-29 Apalutamide (Erleada)

B-30 Bicalutamide (Casodex)

B-31 Bisphosphonate

B-32 Cabazitaxel (Jevtana)

B-33 Darolutamide (Nubeqa)

B-34 Degarelix (Firmagon)

B-35 Docetaxel (Taxotere)

B-36 Enzalutamide (Xtandi)

B-37 Estramustine (Emcyt)

B-38 Estrogens not otherwise specified

B-39 Finasteride (Proscar)

B-40 Flutamide (Eulexin)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-26 - B-56

B-41 Goserelin (Zoladex)

B-42 Ketoconazole (Nizoral)

B-43 Leuprolide (Lupron)

B-44 Lutetium Lu 177 vipivotide tetraxetan infusion (Pluvicto)

B-45 Mitoxantrone (Novantrone)

B-46 Nilutamide (Nilandron)

B-47 Olaparib (Lynparza)

B-48 Prednisone / Steroids not otherwise specified

B-49 Radium-223 infusion (Xofigo)

B-50 Relugolix (Orgovyx)

B-51 Rucaparib (Rubraca)

B-52 Sipuleucel-T (Provenge)

B-53 Talazoparib (Talzenna)

B-54 Other (specify) _____

B-55 Other (specify) _____

B-56 Other (specify) _____

2. Description

2.1. This item collects information on the use of hormonal/endocrine therapy, chemotherapy, infused radiopharmaceuticals, and other systemic agents used to treat prostate cancer (but not agents used to treat symptoms associated with prostate cancer). Enter information for each agent separately. If therapy agents are present in the medical record that are not included in this list, please include these in the "Other Specify" field. Please record information on all systemic therapy, from diagnosis to end of available medical records, **not just the first course of systemic therapy**.

SYSTEMIC THERAPY AGENTS (continued)

ITEM B-26 - B-56

2.2. Code any given agent "00-00-0000-Not given" when the patient did not receive that agent (and it was not recommended). If no systemic therapy was given, then all agents should be coded as "00-00-0000". If any agents were recommended, see "77-77-7777-Refused" and "95-95-9595- Recommended, not given".

2.3. Code "77-77-7777" if an agent was recommended but was not administered because of patient or guardian refusal. If therapy was refused, but it is not known which specific agent was refused, then code "77-77-7777" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended and refused as "77-77-7777."

2.4. Code "95-95-9595 – Recommended, not given" when the records indicate that systemic therapy was recommended but was not given for a reason other than refusal. If it is not known which agents were recommended and not given, then code "95-95-9595" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended and not given as "95-95-9595."

2.5. Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive an agent, but it is unknown if it was actually received. When therapy was recommended, but the agents were not documented, then code "96-96-9696" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended as "96-96-9696."

2.6. Code "97-97-9797 - Unknown" when there is no documentation regarding therapy in the medical records reviewed and there is no information about the therapy from the treating physician.

2.7. Code "99-99-9999" if it is KNOWN that the patient had a particular agent, but the date given cannot be determined. If the exact date of the first administration is unknown, code an estimate. For example, if in history and physical, the physician states the patient had Flutamide beginning two weeks ago, code date of first Flutamide as 14 days prior to that date. If the record states that Flutamide was given recently, code the month and year, but code the day as "99". Coding the closest approximation is preferable to coding unknown.

SYSTEMIC THERAPY AGENTS (continued)

ITEM B-26 - B-56

2.8. When a systemic therapy is administered as one or more arms of a clinical trial and it is not known whether the patient was in that arm, this therapy should be coded as "Unknown if given" (97-97-9797). For example, if a patient were in a trial of new investigational agent vs. casodex, casodex should be coded as "Unknown if given". The new investigational agent should also be listed as "Unknown if given". However, if a patient were in a trial of casodex plus new investigational agent in one arm vs. casodex plus placebo in the other arm, casodex should be coded as given since it is part of both arms. Do not include "placebo" as part of systemic therapies.

2.9. Even if a systemic therapy agent is listed as being administered only for palliative therapy, do not record the name and date of first administration of that agent in this item. Information on systemic agents administered specifically as palliative therapy should be recorded in the palliative care item.

DATE OF FINAL SYSTEMIC THERAPY ADMINISTRATION

ITEM B-57

1. Code Record date of final systemic therapy administration
MM-DD-YYYY
00-00-0000 - No systemic therapy given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
88	88	8888 – Patient remains on therapy
95	95	9595 – Recommended, not given
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the month, day and year on which systemic therapy (including hormone/endocrine therapy, chemotherapy, immunotherapy, and systemic radiation therapy) ended. If the patient has been starting and stopping therapy, then record the last date he stopped the therapy.

2.2. Code “00-00-0000" if no systemic therapy was given.

2.3. Code “77-77-7777” if the records indicate that systemic therapy was recommended, but the patient or patient’s guardian refused.

2.4. Code “88-88-8888 – Patient remains on therapy” if the patient is still taking hormonal/endocrine therapy at the end of the available medical records.

2.5. Code “95-95-9595” if the records indicate that systemic therapy was recommended, but it was not received.

2.6. Code “96-96-9696” if the records indicate that systemic therapy was recommended, but it is unclear whether the patient received it.

2.7. Code “97-97-9797” if it is unknown whether systemic therapy was given.

DATE OF FINAL SYSTEMIC THERAPY ADMINISTRATION (continued)

ITEM B-57

2.8. Code “99-99-9999” if the month, day and year that systemic therapy ended cannot be determined. Code “99” if the month, day or year is unknown. If the exact date is unknown, code an estimate (e.g., if in history and physical, the physician states the patient ended systemic therapy two weeks ago, code date as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states that systemic therapy was ended “recently”, then estimate the month, but not the day. Code “99” if either the month, day or year is unknown.

Common Data Items

A1. SEER Participant ☐☐

A2. Case Number ☐☐☐☐☐☐☐☐

A3. Quality Control ☐

A4. Tumor Record Number ☐☐

A5. Sequence Number ☐☐

A6. Primary Site ☐☐☐

A7. Diagnostic Confirmation ☐

A8. Hospital Code ☐☐☐☐☐☐☐

A9. Insurance Status

	≤ 30 days	> 30 days
No ins/ Self Pay……	☐	☐
Medicare FFS……	☐	☐
Medicare HMO……..	☐	☐
Medicare Part D/PDP…….	☐	☐
Medicare + Private (supp)..	☐	☐
Medicaid……..	☐	☐
Medicaid pending……	☐	☐
Private/IPA/HMO……	☐	☐
Tricare/Other military……..	☐	☐
Veterans Affairs……..	☐	☐
Indian Health Service……	☐	☐
Other (enter text below)….	☐	☐

≤ 30 days _____

> 30 days _____

A10. Treatment Protocol Registration ☐

A11. Protocol Sponsor and Number

☐☐☐☐☐☐☐☐☐☐☐☐

A12. Case Information Verified ☐

A13. Height/Weight

Ht ☐☐☐ Ht Units ☐ _____

Wt ☐☐☐ Wt Units ☐ _____

A14. Date of First Onco Consul ___/___/_____ (mm/dd/yyyy)

A15. Impact of COVID-19 on Cancer Care **AFTER cancer dx**

A. Patient Dx'd with C-19 ☐

B. Date of 1st Pos C-19 Dx ___/___/_____ (mm/dd/yyyy)

C. Date of 1st hosp adm for C-19 ___/___/_____ (mm/dd/yyyy)

A15. Impact of COVID-19 on:

		Other, specify
D. Cancer Diagnosis	☐	_____
E. Surgery to primary site	☐	_____
F. Radiation to primary site	☐	_____
G. Systemic Therapy	☐	_____
H. Palliative Care	☐	_____

A16. Impact of COVID-19 on Finances/Insurance:

Only code info in A-15 through A-17 **for after cancer dx**

A. Patient's finances ☐

B. Patient's Employment ☐

C. Patient's Insurance ☐

A17. Palliative Care **AFTER cancer dx**

A. Palliative Care Received ☐

B. Date of 1st Pall Care ___/___/_____ (mm/dd/yyyy)

C. Counseling/mental health Received ☐

D. Date of 1st couns/mental hlth ___/___/_____ (mm/dd/yyyy)

E. Hospice service/admission ☐

F. Date of 1st hospice/adm ___/___/_____ (mm/dd/yyyy)

A18. NextGen Sequencing (NGS) ☐

A19. Germline Mutations and testing

☐ *BRCA1*	☐ *MSH2*
☐ *BRCA2*	☐ *MSH6*
☐ *APC*	☐ *MUTYH*
☐ *ATM*	☐ *PALB2*
☐ *CHEK2*	☐ *PMS2*
☐ *MLH1*	

Common Data Items (cont)

A20. Smoking/Tobacco Use
- Packs per day ☐☐.☐
- Non-cigarette tobacco use ☐
- Num Years Smoked/non-cig use ☐☐
- Pack years ☐☐
- Smoking Status at DX ☐

A21. Secondhand Smoke Exposure ☐

A22. Family history of cancer
- Same Site ☐
- Breast ☐

PROSTATE CANCER POC 2021

B1. PSA free / total ratio ☐☐.☐

B2. PSA value / date ☐☐☐☐.☐

___ /___ /_____
mm dd yyyy

B3. Biopsy ☐

___ /___ /_____
mm dd yyyy

B4. Number of cores taken / with cancer
- *Taken* ☐☐
- *With cancer* ☐☐

B5. Gleason from BIOPSY
- *Pattern* ☐ + ☐
- *Score* ☐☐

B6. Method of tumor detection ☐

Other _____

B7. Metastasis at diagnosis
- ☐ *Lung*
- ☐ *Distant LNs*
- ☐ *Bone*
- ☐ *Liver*
- ☐ *Other (path)* _____
- ☐ *Other (clin)* _____
- ☐ *Other (clin AND path)* _____

B8. EOD of primary tumor ☐☐☐

B9. TURP ☐

___ /___ /_____
mm dd yyyy

B10. Gleason from TURP
- *Pattern* ☐ + ☐
- *Score* ☐☐

B11. Date of cryosurgery

___ /___ /_____
mm dd yyyy

B12. Type / date of prostatectomy ☐

___ /___ /_____
mm dd yyyy

B13. Gleason from PROSTATECTOMY
- *Pattern* ☐ + ☐
- *Score* ☐☐

B14. Margins / location
- *Margins* ☐
- *Location* ☐ Other _____

B15. Orchiectomy

___ /___ /_____
mm dd yyyy

B16. Lymph nodes positive ☐☐

B17. Lymph nodes examined ☐☐

B18. Somatic Mutations and testing
- ☐ *MSI*
- ☐ *MMR deficiency*
- ☐ *BRCA1*
- ☐ *BRCA2*
- ☐ *ATM*
- ☐ *PALB2*
- ☐ *FANCA*
- ☐ *RAD51D*
- ☐ *CHEK2*
- ☐ *CDK12*
- ☐ *ctDNA*

B19. External radiation ☐

Other _____

B20. Interstitial radiation ☐

Other _____

B21. Total radiation dose / # injections and units

Highest priority modality only *Dose or # inject* ☐☐☐☐.☐

Units ☐ Oth_____

B22. Date radiation began ___ /___ /_____
mm dd yyyy

B23. Date radiation ended ___ /___ /_____
mm dd yyyy

☐ *Completion status*

B24. Active Surveillance/Watchful Waiting/Exp. Mgmt

A. Did patient receive? ☐

B. PSA monitoring frequency ☐

C. Patient's first repeat bx ☐

D. Patient's first repeat imaging ☐

E. Patient stop receiving? ☐

F. Reason pt stopped AS/WW/EM

Enter as many codes as needed

☐☐☐☐☐☐☐☐

Other _____

B25. Metastasis or local recurrence after dx ☐

___ /___ /_____
mm dd yyyy

B57. Date of final systemic therapy ___ /___ /_____
mm dd yyyy

Enter systemic therapy on next page

Notes

Systemic Therapy Agent	**Date** (mm/dd/yyyy)
B26. Abiraterone acetate (Zytiga, Yonsa)	____/____/_____
B27. Combination niraparib plus abiraterone (Akeega)	____/____/_____
B28. Aminoglutethimide (Cytadren)	____/____/_____
B29. Apalutamide (Erleada)	____/____/_____
B30. Bicalutamide (Casodex)	____/____/_____
B31. Bisphosphonate	____/____/_____
B32. Cabazitaxel (Jevtana)	____/____/_____
B33. Darolutamide (Nubeqa)	____/____/_____
B34. Degarelix (Firmagon)	____/____/_____
B35. Docetaxel (Taxotere)	____/____/_____
B36. Enzalutamide (Xtandi)	____/____/_____
B37. Estramustine (Emcyt)	____/____/_____
B38. Estrogens NOS	____/____/_____
B39. Finasteride (Proscar)	____/____/_____
B40. Flutamide (Eulexin)	____/____/_____
B41. Goserelin (Zoladex)	____/____/_____
B42. Ketoconazole (Nizoral)	____/____/_____
B43. Leuprolide (Lupron)	____/____/_____
B44. Lutetium Lu 177 vipivotide tetraxetan infusion (Pluvicto)	____/____/_____
B45. Mitoxantrone (Novantrone)	____/____/_____

Systemic agents continued on next page

Systemic Therapy Agent	Date (mm/dd/yyyy)
B46. Nilutamide (Nilandron)	____/____/_____
B47. Olaparib (Lynparza)	____/____/_____
B48. Prednisone / Steroids NOS	____/____/_____
B49. Radium-223 infusion (Xofigo)	____/____/_____
B50. Relugolix (Orgovyx)	____/____/_____
B51. Rucaparib (Rubraca)	____/____/_____
B52. Sipuleucel-T (Provenge)	____/____/_____
B53. Talazoparib (Talzenna)	____/____/_____
B54. Other, Specify _____	____/____/_____
B55. Other, Specify _____	____/____/_____
B56. Other, Specify _____	____/____/_____

Coding Info

Abstractor ID
☐☐☐☐☐

Date Abstracted
___/___/_____
mm dd yyyy

List all co-morbids on next page

Notes

1.	
2.	
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Abstractor's questions, problems or comments. Attach pages and documentation as needed.

POC DATA ACQUISITION MANUAL

SECTION V

OVARIAN CANCER DATA SET

SECTION V – OVARIAN DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION

ITEM B-1

1. Code MM-DD-YYYY
00-00-0000 – No biopsy

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. This item refers to the date of the first positive biopsy or aspiration. This may be a biopsy/aspiration of the primary site, lymph node or metastatic site that confirmed the diagnosis of ovarian cancer. Code the date the specimen was obtained (NOT the date of the pathology report).

2.2. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy/aspiration date and the Date of Primary Site Surgery will be the same. The first positive biopsy/aspiration may have been done as an outpatient procedure but must be no later than the Date of Primary Site Surgery.

2.3. If there was no biopsy/aspiration done prior to the time of surgical resection, code "00- 00-0000".

2.4. Code “99-99-9999” if it is KNOWN that the patient had a biopsy/aspiration but the day, month and/or year given cannot be determined. If the exact date of the first positive biopsy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a biopsy/aspiration two weeks ago, code date of biopsy as 14 days prior to date of admission). Coding closest approximation is preferable to coding unknown.

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION (continued)

ITEM B-1

2.5. Code “77-77-7777” if patient or the patient’s guardian refused biopsy/aspiration.

2.6. Code “95-95-9595 – Recommended, not performed” when the records indicate that biopsy/aspiration was recommended but was not performed for a reason other than refusal.

2.7. Code “96-96-9696 – Recommended, unknown if performed” if the records indicate that the biopsy/aspiration was recommended but it is unclear whether the patient had the biopsy/aspiration.

2.8. If it is unknown whether a biopsy/aspiration was performed, code “97-97-9797”.

PATHOLOGICAL GRADE

ITEM B-2

1. Code One digit

2. Description

2.1. Use the Grade Pathological codes for the appropriate schema as listed in the Grade Coding Instructions and Tables v3.2.

Schema	Primary Sites	Histologies	Grade Table
Primary Peritoneal Carcinoma	C481, C482	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461	Grade 15
Retroperitoneum	C481, C482	9014	Grade 10
Ovary	C569	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461	Grade 15
Soft Tissue Other	C569, C570	9014	Grade 09
Fallopian Tube	C570	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461	Grade 15

2.2. All pathology reports related to this cancer for the case should be examined.

2.3. Pathological Grade records the grade of a tumor that has been resected and for which no neoadjuvant therapy was administered. If AJCC staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. Record the highest grade documented from any microscopic specimen of the primary site whether from the clinical workup or the surgical resection. Pathological grade must not be blank. Pathological Grade code 3 includes anaplastic.

2.4. Code Pathological Grade as 9 when grade from primary site is not documented; there was no resection of the primary site; neo-adjuvant therapy is followed by a resection; or grade checked "not applicable" on CAP Protocol (if available) and no other grade information is available.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-3
ITEM B-4

1. Code **B-3 – Number of positive regional lymph nodes**

00 – All examined nodes negative
01 – One positive node
02 – Two positive nodes
...
...
90 – 90 or more positive nodes
95 – Positive aspiration or core biopsy of lymph node(s) performed
97 – Positive nodes documented – number unspecified
98 – No nodes examined
99 – Unknown, not stated

B-4 – Number of regional lymph nodes examined

00 – No nodes examined (no nodal dissection performed)
01 – One node examined
02 – Two nodes examined
...
...
90 – 90 or more examined
95 – No regional nodes removed, but aspiration or core biopsy of regional nodes performed
96 – Regional lymph node removal documented as sampling and number of nodes unknown/not stated
97 – Regional lymph node removal documented as dissection and number of nodes unknown/not stated
98 – Regional lymph nodes surgically removed but number of nodes unknown/not stated and not documented as sampling or dissection; nodes examined but number unknown
99 – Unknown/not stated whether nodes examined

2. Description

2.1. For information on which nodes are considered regional, refer to the AJCC Staging Manual 8th Edition. Regional lymph nodes include external/internal iliac; obturator; common iliac; para-aortic; pelvic NOS; and retroperitoneal nodes.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-3 & B-4

2.2. Record the number of regional nodes **examined by a pathologist** and found to contain metastasis. These should be coded based only on data from lymph nodes that are pathologically examined, not from lymph nodes that are clinically examined or examined using imaging procedures.

2.3. Code the number of regional lymph nodes positive in Item B-3 and the number of regional lymph nodes examined in Item B-4. Include all node dissections done during the first course of therapy.

2.4. If more than one dissection was done during the first course of treatment, code the total number of lymph nodes positive and examined.

2.5. If the number of nodes positive was 90 or greater, code Item B-3 as "90". If the number of nodes examined was 90 or greater, code Item B-4 as "90".

2.6. If lymph nodes were known to be positive, but the exact number positive is unknown, code Item B-3 as "97".

2.7. If lymph nodes were known to be positive, but the exact number positive is unknown and the exact number examined is unknown, code Item B-3 as "97" and Item B-4 as "96", "97", or "98".

2.8. If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code Item B-3 "00" and B-4 "96", "97" or "98".

2.9. If no regional node dissection was done or no regional lymph nodes were removed/examined, and there was no aspiration or biopsy, code Item B-3 "98" and Item B-4 "00".

2.10. If it is unknown or not stated whether any nodes were either positive or examined, then code "99" in Items B-3 and B-4.

2.11. If regional lymph nodes were aspirated and no further dissection/sampling was done, code Item B-3 either "00" for negative or "95" if positive and code Item B-4 as "95".

2.12. If both node aspiration and node dissection were performed, code results from the node dissection.

2.13. When there is a difference in the number of nodes positive and/or examined between the body of the pathology report and the final medical report, code the information from the final medical report.

SOMATIC (TUMOR CELL) MUTATIONS AND TESTING

ITEM B-5

1. Code

0 – Test not performed
1 – One or more of specified test performed, all positive
2 – One or more of specified test performed, all negative
3 – More than one of specified test performed, initially positive and subsequently negative
4 – More than one of specified test performed, initially negative and subsequently positive
5 – One or more of specified test performed, only positive finding is variants of unknown significance (VUS)
8 – Test performed, result unknown
9 – Unknown if test performed/no mention

Code separately for each of the following tests
MSI/Microsatellite instability (MSI-H)
MMR deficiency/Mismatch repair deficiency
BRCA1
BRCA2
Homologous recombination deficiency (HRD)
p53
PAX8
PDL-1
Circulating tumor DNA (ctDNA)

2. Description

2.1. Molecular marker or mutations status information can come from either the primary tumor or from metastases; if tests are performed on either the primary tumor or a metastasis, the specified marker/mutation should be coded using the values indicated.

2.2. If the test was not performed, then code "0 – Test not performed".

2.3. If a test was performed one or more times and all test results were positive, code that test as "1 – One or more of specified test performed, all positive".

2.4. If a test was performed one or more times and all test results were negative, code that test as "2 – One or more of specified test performed, all negative".

2.5. If a test was performed more than one time and the test results were positive the first time but were negative for any subsequent test, code that test as "3 – More than one of specified test performed, initially positive and subsequently negative".

SOMATIC (TUMOR CELL) MUTATIONS AND TESTING (continued)

ITEM B-5

2.6. If a test was performed more than one time and the test results were negative the first time but were positive for any subsequent test, code that test as "4 – More than one of specified test performed, initially negative and subsequently positive".

2.7. If a test was performed one or more times and the only positive result was variants of unknown significance (VUS), then code "5". Use this code if there were negative findings in addition to positive VUS.

2.8. If there is mention of the test being performed in the record but no results, then code "8 – Test performed, results unknown".

2.9. If a patient received a panel of multiple tests (also called a "gene panel") and the specified mutation is listed as being part of the panel, assume that it was tested for. However, if the result is not listed, don't assume the test result was negative. If the specified test result is not listed, coded this as "8 – One or more test performed, result unknown".

2.10. If there is no mention of the test in the records and no indication whether or not the test was performed, then code "9 – Unknown if test performed/no mention".

METASTASIS AT DIAGNOSIS / PERITONEAL CAVITY METASTASIS

ITEM B-6

1. Code **A. Non-peritoneal metastasis at diagnosis**

0 – No evidence of metastasis at the site
1 – Yes, only pathologic confirmation of metastasis at the site
2 – Yes, only clinical confirmation of metastasis at the site
3 – Yes, both clinical and pathologic confirmation of metastasis at the site
9 – Unknown if metastasis at the site

Sites
Lung
Distant lymph node(s)
Bone
Liver
Brain/Nervous System
Spleen
Intestines
Other, specify (pathologic) _____
Other, specify (clinical) _____
Other, specify (clinical and pathologic) _____

B. Peritoneal cavity (pelvis and abdomen) metastasis / peritoneal carcinomatosis at diagnosis

0 – No evidence of at diagnosis
1 – Yes, only pathologic confirmation at diagnosis
2 – Yes, only clinical confirmation at diagnosis
3 – Yes, both clinical and pathological confirmation at diagnosis
9 – Unknown if present at diagnosis

2. Description

2.1. Refer to the 2021 SEER Program Coding and Staging Manual for complete details. In Item A, code information about non-peritoneal metastasis identified at the time of diagnosis. Information about metastatic involvement may be clinical or pathologic. These codes are NOT the codes from the SEER Manual—the POC codes are expanded to capture clinical and pathologic information. This information should not be taken from autopsy records.

2.2. In Item A, code "0 – No" if there is no evidence of distant metastasis in the medical record or imaging reports.

METASTASIS AT DIAGNOSIS/PERITONEAL CAVITY METASTASIS (continued)

ITEM B-6

2.3. In Item A, code "1 – Yes, only pathologic confirmation of metastasis at the site" when there is pathologic but no clinical evidence of distant metastasis. Pathologic confirmation requires a biopsy positive for cancer at the metastatic site and may be reported in a pathology report or surgical records.

2.4. In Item A, code "2 – Yes, only clinical confirmation of metastasis at the site" when there is clinical but no pathologic evidence of distant metastasis. Clinical confirmation can be derived from documentation in patient history or physical examination and imaging reports. However, imaging of distant organs is not required.

2.5. In Item A, code "3 – Yes, both clinical and pathologic confirmation of metastasis at the site" when there is clinical and pathologic confirmation of distant metastasis.

2.6. In Item A, code "9 – Unknown" if it is unknown whether there is metastasis at the site. If there is no information about whether the patient had any metastatic disease, all sites should be coded "9 – Unknown."

2.7. In Item B, record information on peritoneal carcinomatosis or metastasis at diagnosis in the same manner that Item A was coded. If there was evidence of peritoneal metastasis or carcinomatosis, record whether there was pathologic confirmation, clinical confirmation, or both. If there was no evidence or no mention of peritoneal carcinomatosis or metastasis in the medical record or imaging reports, then code "0". If it is unknown, then code "9".

HYSTERECTOMY PRIOR TO CANCER DIAGNOSIS

ITEM B-7

1. Code 0 – No
1– Yes
9 – Unknown/Not stated

2. Description

2.1. Please review the entire medical record for this information. It may be found in the history and physical, the physician notes, the nurses' notes, or the operative report.

2.2. Code "0 – No" if patient has not had a hysterectomy prior to this diagnosis of ovarian cancer.

2.3. Code "1 – Yes" if patient has had a hysterectomy prior to this diagnosis of ovarian cancer.

2.4. Code "9 – Unknown/ not stated" if it is unknown or not stated in the record if the patient had a hysterectomy prior to this diagnosis of ovarian cancer.

2.5. Review the medical record not just for the word hysterectomy, but other indications as well e.g., prior TAH – total abdominal hysterectomy.

OVARIAN SURGERY PRIOR TO CANCER DIAGNOSIS

ITEM B-8

1. Code **Select All That Apply**

a – No ovarian procedure performed *(do not select other options)*
b – Left ovary removed (left oophorectomy)
c – Right ovary removed (right oophorectomy)
d – One or more ovaries removed but unknown which ovary(ies) removed (oophorectomy, unknown if unilateral/bilateral)
e – One or both fallopian tubes removed (salpingectomy)
f – Tubal ligation
g – Unknown/no mention if any ovarian surgery or tubal ligation prior to cancer diagnosis

2. Description

2.1. Please review the entire medical record for this information. It may be found in the history and physical, the physician notes, the nurses' notes or the operative report.

2.2. Select "a – No ovarian procedure performed" if no oophorectomy, salpingectomy, salpingo-oophorectomy, or tubal ligation has been performed on the patient prior to this diagnosis of ovarian cancer. All other response options should not be selected.

2.3. Select "b – Left ovary removed" if the left ovary was removed prior to this diagnosis of ovarian cancer. If both the left and right ovaries were removed prior to this diagnosis of ovarian cancer (i.e., bilateral oophorectomy), both response (b) and (c) should be selected.

2.4. Select "c – "Right ovary removed" if the right ovary was removed prior to this diagnosis of ovarian cancer. If both the left and right ovaries were removed prior to this diagnosis of ovarian cancer (i.e., bilateral oophorectomy), both response (b) and (c) should be selected.

2.5. Select "d – One or more ovaries removed but unknown which ovary(ies) removed" if the record states the patient had an oophorectomy but does not specify if the left, right, or both ovaries were removed prior to this diagnosis of ovarian cancer. If (d) is selected, neither (b) nor (c) should be selected.

2.6. Select "e – One or both fallopian tubes removed" if one or both fallopian tubes were removed prior to this cancer diagnosis. If both ovaries and one or more fallopian tubes were removed prior to this cancer diagnosis, responses (b), (c), and (e) should all be selected.

OVARIAN SURGERY PRIOR TO CANCER DIAGNOSIS (continued)

ITEM B-8

2.7. Select “f – Tubal ligation” if there was tubal ligation but prior to the diagnosis of cancer.

2.8. Code “g – Unknown/no mention” if it is unknown if the patient had any ovarian/fallopian surgery or tubal ligation prior to this diagnosis of ovarian cancer, or it is not mentioned in the patient’s record.

METHOD OF TUMOR DETECTION

ITEM B-9

1. Code

1 – Abdominal symptoms (bloating, constipation, abdominal symptoms)
2 – Non-Abdominal signs/symptoms
3 – Non-cancer ovarian surgery
4 – Incidental finding on imaging performed for other symptoms/conditions
5 – Other, specify_____
9 – Unknown/Not specified

2. Description

2.1. Code the method by which the tumor was initially detected. This refers to the first notice of an ovarian tumor, NOT the diagnostic procedures that followed. If there were multiple methods of tumor detection, lower codes have priority over higher codes. For example, if there were both abdominal symptoms (code 1) and non-abdominal symptoms (code 2), then use code "1-Abdominal symptoms".

2.2. Code "1 – Abdominal signs/symptoms" when the patient reported signs/symptoms such as bloating, constipation, or abdominal distention/discomfort/pain.

2.3. Code "2 – Non-Abdominal signs/symptoms" when the patient reported signs/symptoms unrelated to the abdomen.

2.4. Code "3 – Non-cancer ovarian surgery" when the patient's cancer was detected during an oophorectomy, salpingectomy, salpingo-oophorectomy, or tubal ligation that was performed without (i.e., prior to) this diagnosis of ovarian cancer. There may have been other ovarian/fallopian surgeries performed (coded in Item B-8) prior to the surgery when the cancer was diagnosed.

2.5. Code "4 – Incidental finding on imaging performed for other symptoms/conditions" when the cancer was first detected following an imaging study (X-ray, ultrasound, MRI, PET, CAT scan) performed for symptoms or conditions unrelated to ovarian cancer.

2.6. Code "5 – Other, specify" when the tumor was discovered by some other means. Specify the method of discovery. Symptoms should not be entered in Other, Specify.

2.7. Code "9 – Unknown/Not specified" when it cannot be determined from the records how the tumor was initially detected.

EOD OF PRIMARY TUMOR

ITEM B-10

1. Code https://staging.seer.cancer.gov/eod_public/list/3.2/

2. Description

2.1. See site-specific EOD Primary Tumor codes for the following schemas based on primary site and histology:

Schema	Primary Sites	Histologies
Primary Peritoneal Carcinoma	C481, C482	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461
Retroperitoneum	C481, C482	9014
Ovary	C569	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461
Soft Tissue Other	C569, C570	9014
Fallopian Tube	C570	8020, 8021, 8380, 8381, 8382, 8383, 8440, 8441, 8450, 8461

PRIMARY SITE SURGERY AND DATE

ITEM B-11

1. Code Surgery Code 00-99
Refer to SPCSM 2021, Appendix C
Ovary (C569) Surgery Codes
Peritoneum and Fallopian (C481, C482, C570) Surgery Codes

MM-DD-YYYY
00-00-0000 - No primary site surgery

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Enter the site-specific surgery code as defined in SEER Program Coding and Staging Manual 2021, Appendix C for the appropriate primary site. This is only for the initial **(first course)** surgery to the **primary site**.

- Ovary (C569): See Ovarian Surgery Codes
- Peritoneum (C481, C482) and Fallopian Tube (C570): See All Other Sites Surgery Codes

2.2. Enter the date on which the most definitive surgery of the primary site was performed. Code "00-00-0000" if no surgery to the primary site was performed.

2.3. If the patient or patient's guardian refused surgery to the primary site, then code "77-77- 7777 – Patient/guardian refused".

2.4. Code "95-95-9595 – Recommended, not performed" when the records indicate that surgery was recommended but was not performed for a reason other than refusal.

PRIMARY SITE SURGERY AND DATE (continued)

ITEM B-11

2.5. If surgery to the primary site was recommended, but it is unknown if it was performed, then code "96-96-9696 – Recommended, unknown if given".

2.6. If it is unknown whether the patient had surgery to the primary site, then code "97-97-9797-Unknown if performed".

2.7. Code "99-99-9999" if it is KNOWN that the patient had surgery to the primary site, but the day, month and/or year given cannot be determined. If the exact date of the surgery is unknown, then code an estimate. For example, if in history and physical, the physician states the patient had surgery two weeks ago, then code the date of surgery as 14 days prior. Coding the closest approximation is preferable to coding unknown.

RESIDUAL TUMOR AFTER CANCER-DIRECTED SURGERY

ITEM B-12

1. Code

0 – No primary site surgery
1 – No visible residual tumor
2 – Only microscopic residual tumor
3 – Visible residual tumor, NOS
4 – Visible residual tumor, no single lesion > 1 cm
5 – Visible residual tumor > 1 cm
6 – Visible residual tumor, size not stated, but stated as ‘sub-optimal’
7 – Visible residual tumor, size not stated, but stated as ‘optimal’
8 – Surgery recommended, unknown if performed
9 – Unknown/no mention

2. Description

2.1. Code "0 – No primary site surgery" when Item B-11 is coded "00-00-0000”, “77-77-7777”, or “95-95-9595”.

2.2. Code “1 – No visible residual tumor” when the surgeon or pathologist indicates no residual tumor remains after the cancer-directed surgery.

2.3. Code "2 – Only microscopic residual tumor" when the surgeon or pathologist reports that there is only microscopic residual tumor remaining.

2.4. Code "3 – Visible residual tumor, NOS" when the surgeon or pathologist reports that there is tumor remaining but does not document the amount.

2.5. Code “4 – Visible residual tumor, no single lesion > 1 cm” when the surgeon or pathologist indicates that there is tumor remaining, but no single lesion is greater than 1 cm.

2.6. Code “5 – Visible residual tumor > 1 cm” when the surgeon or pathologist indicates that there is tumor remaining and one or more lesions are greater than 1 cm.

2.7. Code “6 – Visible residual tumor, size not stated, but stated as ‘sub-optimal’” when the surgeon or pathologist indicates that there is tumor remaining, but no size is given, and it is stated that the tumor remaining is sub-optimal.

2.8. Code “7 – Visible residual tumor, size not stated, but stated as ‘optimal’” when the surgeon or pathologist indicates that there is tumor remaining, but no size is given, and it is stated that the tumor remaining is optimal.

RESIDUAL TUMOR AFTER CANCER-DIRECTED SURGERY (continued)

ITEM B-12

2.9. Code “8 – Surgery recommended, unknown if performed” if the physician recommended surgery but it is unknown whether it was performed. Use this code when cancer-directed surgery (Item B-11) is coded “96-Recommended, unknown if performed”.

2.10. Code "9 – Unknown, not stated" when there is no information in the pathology report regarding residual tumor and the surgeon does not document residual tumor in the operative report. Use this code when it is unknown whether cancer-directed surgery was performed (Item B-11 is coded “97-97-9797”).

DATE RADIATION BEGAN

ITEM B-13

1. Code MM-DD-YYYY
00-00-0000 - No radiation given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not performed
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the month, day and year on which the first radiation to the PRIMARY SITE (i.e., the ovary) was begun any time after diagnosis.

2.2. Code “00-00-0000” if no radiation was performed or recommended.

2.3. Code “77-77-7777” if the records indicate that radiation was recommended, but the patient or patient’s guardian refused.

2.4. Code “96-96-9696” if the records indicate that radiation was recommended, but it is unclear whether the patient had radiation.

2.5. Code “97-97-9797” if it is unknown whether radiation was performed.

2.6. Code “99-99-9999” if the month, day and year the radiation began cannot be determined. If the exact date is unknown, code an estimate (e.g., if in history and physical, the physician states the patient started radiation therapy two weeks ago, code date of start of radiation therapy as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states radiation therapy started “recently”, then estimate the month, but not the day. Code “99” if either the month, day or year is unknown.

METASTASIS/RECURRENCE OR PERITONEAL SPREAD AFTER DIAGNOSIS

ITEM B-14

1. Code

i) Non-peritoneal metastasis/recurrence identified **after** diagnosis

0 – No evidence of metastasis/recurrence after diagnosis
1 – Yes, metastasis/recurrence identified after diagnosis
8 – N/A (Patient had non-peritoneal metastatic disease at diagnosis)
9 – Unknown if metastasis/recurrence identified after diagnosis

ii) Date first non-peritoneal metastasis/recurrence identified **after** diagnosis

MM-DD-YYYY
00-00-0000 – No evidence of non-peritoneal metastasis/recurrence; N/A; or Unknown (Codes 0, 8, 9)

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

iii) Peritoneal cavity (pelvis and abdomen) metastasis / peritoneal carcinomatosis identified after diagnosis

0 – No evidence of peritoneal metastasis or carcinomatosis after diagnosis
1 – Yes, peritoneal metastasis or carcinomatosis identified after diagnosis
8 – N/A (Patient had peritoneal metastasis or carcinomatosis at diagnosis)
9 – Unknown if peritoneal metastasis or carcinomatosis identified after diagnosis

iv) Date first peritoneal metastasis / peritoneal carcinomatosis identified **after** diagnosis

MM-DD-YYYY
00-00-0000 – No evidence of peritoneal metastasis/carcinomatosis; N/A; or Unknown (Codes 0, 8, 9)

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

METASTASIS/RECURRENCE OR PERITONEAL SPREAD AFTER DIAGNOSIS (cont)

ITEM B-14

2. Description

2.1. This item collects information on whether a cancer metastasis/recurrence is identified after the initial tumor diagnostic work-up. Peritoneal and non-peritoneal metastasis are collected separately.

2.2. For item (i), Code "8 – N/A" if at initial diagnosis the patient was diagnosed with metastatic disease (M-stage M1 or coded as "Yes" in Item B-6, Item A, "METASTASIS AT DIAGNOSIS").

2.3. Code "0 – No" if there is no evidence of metastasis/recurrence in the medical record or imaging reports after the initial tumor diagnostic work-up. The initial tumor diagnostic work-up is not just the initial biopsy but also includes subsequent imaging studies to determine the initial stage of the patient's cancer. This option should be selected only if the patient did not have metastatic disease at diagnosis. If the patient had metastatic disease at diagnosis (M-stage M1 or coded as "Yes" in Item B-6, Item A), instead use code "8 – N/A".

2.4. Code "1 – Yes, metastasis/recurrence identified after diagnosis" when there is clinical or pathologic evidence of metastasis/recurrence **after** diagnosis for patients who did not have an initial diagnosis of metastatic cancer.

2.5. Code "9 – Unknown" if it is unknown whether there is metastasis or recurrence after diagnosis.

2.6. For item (ii), code the first date that the non-peritoneal metastasis/recurrence was identified after initial diagnosis listed in the medical record.

2.7. For item (iii), code whether peritoneal metastasis or carcinomatosis was identified after diagnosis. If there was peritoneal metastasis or carcinomatosis identified AT diagnosis, then code "8 – N/A".

2.8. Code "0 – No" if there is no evidence of peritoneal metastasis or carcinomatosis in the medical record or imaging reports after the initial tumor diagnostic work-up. Code "1 – Yes" if peritoneal metastasis or carcinomatosis was identified after the initial tumor diagnostic work-up.

2.9. For item (iv), code the first date that the peritoneal metastasis/carcinomatosis was identified after initial diagnosis listed in the medical record.

TYPE OF PHYSICIAN SPECIALTY

ITEM B-15

1. Code

1 – Gynecologic oncologist
2 – Surgical oncologist
3 – Obstetrician gynecologist
4 – General surgeon
5 – Urologist
6 – Medical oncologist
7 – Internist
8 – Other specify _____
9 – Unknown
0 – None other

2. Description

2.1. This item is to describe the type of specialty of the physician(s) treating the patient. The patient may see more than one physician during her initial therapy. This item refers to the physician who performs the most definitive therapy, usually surgery, and the physician who prescribes the systemic therapy: chemotherapy, hormonal therapy, immunotherapy or other systemic therapy.

2.2. CODE UP TO 2 PHYSICIANS. THIS IS A HIERARCHICAL LISTING. CODE THE PHYSICIANS WITH THE LOWER NON-ZERO NUMBERS FIRST.

2.3. In the first box, record the specialty of the physician performing the most definitive therapy. This will most often be the surgeon performing the definitive surgery for ovarian cancer in the first column. He or she may be a general surgeon or a physician with special surgical training, such as a surgical oncologist. If the woman does not have surgery, code the type of specialty of the physician who provides the most definitive therapy, such as the medical oncologist.

2.4. In the second box, record the specialty of the physician providing systemic therapy after the most definitive SURGERY. This may be a medical oncologist or gynecologic oncologist who is providing the systemic therapy or the physician providing follow-up care.

2.5. If the physician specialty is not listed, please code “8 – Other specify” and enter the physician specialty.

TYPE OF PHYSICIAN SPECIALTY (continued)

ITEM B-15

2.7. Information about medical specialty may be found under the "medical specialty" on the AMA website. The hospital website might also provide information about the training of physicians associated with the hospital. There are other directories such as the "Society of Gynecologic Oncologist" http://www.sgo.org/directory/search.asp. This also allows you to search for "related specialties."

2.8. Not all patients will have cancer-directed surgery. If the patient does not have cancer-directed surgery, code the specialties of other physicians providing therapy.

2.9. If the woman sees only one doctor, code "0 – none other" in the second box.

SYSTEMIC THERAPY AGENTS / ADMINISTRATION

ITEM B-16 THROUGH B-53

1. Code ADMINISTRATION

0 – Not given
1 – Yes, given IV
2 – Yes, given IP
3 – Yes, given both IV and IP
4 – Yes, oral administration
5 – Yes, given oral and IV or IP
6 – Yes, given but route of administration unknown
7 – Patient or patient's guardian refused systemic therapy
8 – Recommended, unknown if given
9 – Unknown, not stated if systemic therapy agents given

AGENT
MM-DD-YYYY
00-00-0000 - No systemic therapy given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
95	95	9595 – Recommended, not given
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

B-16 Albumin bound paclitaxel (nab-paclitaxel, Abraxane)

B-17 Altretamine (Hexalen)

B-18 Anastrozole (Arimidex)

B-19 Bevacizumab (Alymsys, Avastin, Mvasi, Zirabev)

B-20 Capecitabine (Xeloda)

B-21 Carboplatin (Paraplatin)

SYSTEMIC THERAPY/ADMINISTRATION (continued)

ITEMS B-16 through B-53

B-22 Cisplatin (Platinol)

B-23 Cyclophosphamide (Cytoxan)

B-24 Docetaxel (Taxotere)

B-25 Doxorubicin (Adriamycin)

B-26 Doxorubicin Hydrochloride Liposome (Doxil, Lipodox 50)

B-27 Entrectinib (Rozlytrek)

B-28 Etoposide (VP16)

B-29 Exemestane (Aromasin)

B-30 Gemcitabine (Gemzar, Infugem)

B-31 Goserelin (Zoladex)

B-32 Hexamethylmelamine (Hexalen)

B-33 Ifosfamide (Ifex)

B-34 Irinotecan (CPT-11, Camptosar)

B-35 Larotrectinib (Vitrakvi)

B-36 Letrozole (Femara)

B-37 Leuprolide (Lupron)

B-38 Megestrol acetate (Megace)

B-39 Melphalan (Alkeran)

B-40 Mirvetuximab Soravtansine-gynx (Elahere)

B-41 Niraparib (Zejula)

B-42 Olaparib (Lynparza)

B-43 Paclitaxel (Taxol)

B-44 Pembrolizumab (Keytruda)

B-45 Pemetrexed (Alimta)

B-46 Rucaparib (Rubraca)

B-47 Tamoxifen (Nolvadex)

B-48 Thiotepa (Tepadina)

B-49 Topotecan (Hycamtin)

B-50 Vinorelbine (Navelbine)

B-51 Other specify _____

B-52 Other specify _____

B-53 Other specify _____

This list is by no means complete and if other chemotherapeutic agents are found, please list them as well.

2. Description

2.1. The definition of systemic therapy is treatment that reaches cells throughout the body by traveling through the bloodstream. This item collects information on the use of hormonal/endocrine therapy, chemotherapy, and other systemic agents used to treat ovarian cancer (but not agents used to treat symptoms associated with ovarian cancer).

2.2. Enter information for each agent separately. If therapy agents are present in the medical record that are not included in this list, please include these in the "Other Specify" field. Please record information on all systemic therapy, from diagnosis to end of available medical records, **not just the first course of systemic therapy**.

2.3. Code Administration as "0 – Not given" in the one-digit field when the patient did not receive the systemic therapy agent. If no systemic therapy was given, all agents must be coded "0", unless the patient or patient's guardian refused systemic therapy. (See also "Code 7 - Patient or patient's guardian refused systemic therapy.")

2.4. Code Administration as "1 – Yes, given IV" when a particular systemic therapy agent was given intravenously.

2.5. Code Administration as "2 – Yes, given IP" when a particular agent was given intraperitoneally.

2.6. Code Administration as "3 – Yes, given both IV and IP" when a particular agent was given intravenously and intraperitoneally.

2.7. Code Administration as "4 – Yes, oral administration" when a particular agent was given orally.

2.8. Code Administration as "5 – Yes, given oral and IV or IP " when a particular agent was given orally AND was given IV or IP.

SYSTEMIC THERAPY AGENTS / ADMINISTRATION (continued)

ITEMS B-16 - B-53

2.9. Code Administration as "6 – Yes, given, but route of administration unknown" when an agent is given, but it is unknown whether it was given orally, IV, or IP.

2.10. Code Administration as "9 – Unknown, not stated" when there is no documentation regarding systemic therapy in the medical records reviewed and the physician does not provide any information about systemic therapy.

2.11. Code any given agent "00-00-0000 – Not given" when the patient did not receive that agent (and it was not recommended). Code Administration as "0 – Not Given". If no systemic therapy was given, then all agents should be coded as "00-00-0000". If any agents were recommended, see "77-77-7777 – Refused" and "95-95-9595-Recommended, not given".

2.12. Code "77-77-7777" if an agent was recommended but was not administered because of patient or guardian refusal. If therapy was refused, but it is not known which specific agent was refused, then code "77-77-7777" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended and refused as "77-77-7777." Code Administration as "7 – Refused".

2.13. Code "95-95-9595 – Recommended, not given" when the records indicate that systemic therapy was recommended but was not given for a reason other than refusal. If it is not known which agents were recommended and not given, then code "95-95-9595" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended and not given as "95-95-9595." Code Administration as "0 – Not given".

2.14. Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive an agent, but it is unknown if it was actually received. When therapy was recommended, but the agents were not documented, then code "96-96-9696" in the first "Other Specify" field and enter the text "unknown agent". Otherwise, code each specific agent known to have been recommended as "96-96-9696." Code Administration as "8 – Recommended, unknown if given".

2.15. Code "97-97-9797 - Unknown" when there is no documentation regarding therapy in the medical records reviewed and there is no information about the therapy from the treating physician. Code Administration as "9 – Unknown/not stated".

SYSTEMIC THERAPY AGENTS / ADMINISTRATION (continued)

ITEMS B-16 – B-53

2.16. Code "99-99-9999" if it is KNOWN that the patient had a particular agent, but the date given cannot be determined. If the exact date of the first administration is unknown, code an estimate. For example, if in history and physical, the physician states the patient had Flutamide beginning two weeks ago, code date of first Flutamide as 14 days prior to that date. If the record states that Flutamide was given recently, code the month and year, but code the day as "99". Coding the closest approximation is preferable to coding unknown.

2.17. When a systemic therapy is administered as one or more arms of a clinical trial and it is not known whether the patient was in that arm, this therapy should be coded as "Unknown if given" (97-97-9797). For example, if a patient were in a trial of new investigational agent vs. casodex, casodex should be coded as "Unknown if given". The new investigational agent should also be listed as "Unknown if given". However, if a patient were in a trial of casodex plus new investigational agent in one arm vs. casodex plus placebo in the other arm, casodex should be coded as given since it is part of both arms. Do not include "placebo" as part of systemic therapies.

2.18. Even if a systemic therapy agent is listed as being administered only for palliative therapy, do not record the name and date of first administration of that agent in this item. Information on systemic agents administered specifically as palliative therapy should be recorded in the palliative care item.

DATE OF FINAL SYSTEMIC THERAPY ADMINISTRATION

ITEM B-54

1. Code Record date of final systemic therapy administration
MM-DD-YYYY
00-00-0000 - No systemic therapy given

Month	**Day**	**Year**
01 – January	01	Use 4-digit year
02 – February	02	
…	…	
12 – December	31	
77	77	7777 – Patient or Guardian refused
88	88	8888 – Patient remains on therapy
95	95	9595 – Recommended, not given
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 – Month Unknown	99 – Day Unknown	9999 – Year Unknown

2. Description

2.1. Record the month, day and year on which systemic therapy (including hormone/endocrine therapy, chemotherapy, immunotherapy, and systemic radiation therapy) ended. If the patient has been starting and stopping therapy, then record the last date she stopped the therapy.

2.2. Code “00-00-0000" if no systemic therapy was given.

2.3. Code “77-77-7777” if the records indicate that systemic therapy was recommended, but the patient or patient’s guardian refused.

2.4. Code “88-88-8888 – Patient remains on therapy” if the patient is still taking hormonal/endocrine therapy at the end of the available medical records.

2.5. Code “95-95-9595” if the records indicate that systemic therapy was recommended, but it was not received.

2.6. Code “96-96-9696” if the records indicate that systemic therapy was recommended, but it is unclear whether the patient received it.

2.7. Code “97-97-9797” if it is unknown whether systemic therapy was given.

DATE OF FINAL SYSTEMIC THERAPY ADMINISTRATION (continued)

ITEM B-54

2.8. Code “99-99-9999” if the month, day and year that systemic therapy ended cannot be determined. Code “99” if the month, day or year is unknown. If the exact date is unknown, code an estimate (e.g., if in history and physical, the physician states the patient ended systemic therapy two weeks ago, code date as 14 days prior to date of note). Coding the closest approximation is preferable to coding unknown. If it states that systemic therapy was ended “recently”, then estimate the month, but not the day. Code “99” if either the month, day or year is unknown.

Common Data Items

A1. SEER Participant ☐☐

A2. Case Number ☐☐☐☐☐☐☐☐

A3. Quality Control ☐

A4. Tumor Record Number ☐☐

A5. Sequence Number ☐☐

A6. Primary Site ☐☐☐

A7. Diagnostic Confirmation ☐

A8. Hospital Code ☐☐☐☐☐☐☐

A9. Insurance Status

	≤ 30 days	> 30 days
No ins/ Self Pay……	☐	☐
Medicare FFS……	☐	☐
Medicare HMO……..	☐	☐
Medicare Part D/PDP…….	☐	☐
Medicare + Private (supp)..	☐	☐
Medicaid……..	☐	☐
Medicaid pending……	☐	☐
Private/IPA/HMO……	☐	☐
Tricare/Other military……..	☐	☐
Veterans Affairs……..	☐	☐
Indian Health Service……	☐	☐
Other (enter text below)….	☐	☐

≤ 30 days _____

> 30 days _____

A10. Treatment Protocol Registration ☐

A11. Protocol Sponsor and Number

☐☐☐☐☐☐☐☐☐☐☐☐

A12. Case Information Verified ☐

A13. Height/Weight

Ht ☐☐☐ Ht Units ☐ _____

Wt ☐☐☐ Wt Units ☐ _____

A14. Date of First Onco Consul ___/___/_____ (mm/dd/yyyy)

A15. Impact of COVID-19 on Cancer Care **AFTER cancer dx**

A. Patient Dx'd with C-19 ☐

B. Date of 1st Pos C-19 Dx ___/___/_____ (mm/dd/yyyy)

C. Date of 1st hosp adm for C-19 ___/___/_____ (mm/dd/yyyy)

A15. Impact of COVID-19 on:

		Other, specify
D. Cancer Diagnosis	☐	_____
E. Surgery to primary site	☐	_____
F. Radiation to primary site	☐	_____
G. Systemic Therapy	☐	_____
H. Palliative Care	☐	_____

A16. Impact of COVID-19 on Finances/Insurance:

Only code info in A-15 through A-17 **for after cancer dx**

A. Patient's finances ☐

B. Patient's Employment ☐

C. Patient's Insurance ☐

A17. Palliative Care **AFTER cancer dx**

A. Palliative Care Received ☐

B. Date of 1st Pall Care ___/___/_____ (mm/dd/yyyy)

C. Counseling/mental health Received ☐

D. Date of 1st couns/mental hlth ___/___/_____ (mm/dd/yyyy)

E. Hospice service/admission ☐

F. Date of 1st hospice/adm ___/___/_____ (mm/dd/yyyy)

A18. NextGen Sequencing (NGS) ☐

A19. Germline Mutations and testing

☐ *BRCA1*	☐ *MSH2*
☐ *BRCA2*	☐ *MSH6*
☐ *APC*	☐ *MUTYH*
☐ *ATM*	☐ *PALB2*
☐ *CHEK2*	☐ *PMS2*
☐ *MLH1*	

Common Data Items (cont)

A20. Smoking/Tobacco Use
- Packs per day ☐☐.☐
- Non-cigarette tobacco use ☐
- Num Years Smoked/non-cig use ☐☐
- Pack years ☐☐
- Smoking Status at DX ☐

A21. Secondhand Smoke Exposure ☐

A22. Family history of cancer
- Same Site ☐
- Breast ☐

OVARIAN CANCER POC 2021

B1. Date of first positive bx/asp ___/___/_____ (mm/dd/yyyy)

B2. Pathological grade ☐

B3. Lymph nodes positive ☐☐

B4. Lymph nodes examined ☐☐

B5. Somatic Mutations and testing

- ☐ *MSI*
- ☐ *MMR deficiency*
- ☐ *BRCA1*
- ☐ *BRCA2*
- ☐ *HRD*
- ☐ *p53*
- ☐ *PAX8*
- ☐ *PDL-1*
- ☐ *ctDNA*

B6. Metastasis at diagnosis/Peritoneal Cavity Mets

A. Non-peritoneal mets at dx
- ☐ *Lung*
- ☐ *Distant LNs*
- ☐ *Bone*
- ☐ *Liver*
- ☐ *Brain/ nervous system*
- ☐ *Spleen*
- ☐ *Intestines*
- ☐ *Other (path)* _____
- ☐ *Other (clin)* _____
- ☐ *Other (clin & path)* _____

B. Peritoneal mets/carcinomatosis at dx ☐

B7. Hysterectomy prior to dx ☐

B8. Ovarian surgery prior to dx ☐☐☐☐

B9. Method of tumor detection ☐

Other _____

B10. EOD of primary tumor ☐☐☐

B11. Primary site surgery and date ☐☐

___/___/_____ (mm/dd/yyyy)

B12. Residual tumor after surgery ☐

B13. Date radiation to primary site ___/___/_____ (mm/dd/yyyy)

B14. Metastasis/peritoneal spread after dx

i). Non-peritoneal mets after dx ☐

ii). Date ___/___/_____ (mm/dd/yyyy)

iii). Peritoneal mets/carcinomatosis after dx ☐

iv). Date ___/___/_____ (mm/dd/yyyy)

B15. Type of physician specialty ☐ 1st ☐ 2nd

Other _____

B54. Date of final systemic therapy ___/___/_____ (mm/dd/yyyy)

Enter systemic therapy on next page

Notes

Systemic Therapy Agent	Date (mm/dd/yyyy)	Mode of Admin
B16. Albumin bound paclitaxel (nab-paclitaxel, Abraxane)	____/____/_____	☐
B17. Altretamine (Hexalen)	____/____/_____	☐
B18. Anastrozole (Arimidex)	____/____/_____	☐
B19. Bevacizumab (Alymsys, Avastin, Mvasi, Zirabev)	____/____/_____	☐
B20. Capecitabine (Xeloda)	____/____/_____	☐
B21. Carboplatin (Paraplatin)	____/____/_____	☐
B22. Cisplatin (Platinol)	____/____/_____	☐
B23. Cyclophosphamide (Cytoxan)	____/____/_____	☐
B24. Docetaxel (Taxotere)	____/____/_____	☐
B25. Doxorubicin (Adriamycin)	____/____/_____	☐
B26. Doxorubicin Hydrochloride Liposome (Doxil, Lipodox 50)	____/____/_____	☐
B27. Entrectinib (Rozlytrek)	____/____/_____	☐
B28. Etoposide (VP16)	____/____/_____	☐
B29. Exemestane (Aromasin)	____/____/_____	☐
B30. Gemcitabine (Gemzar, Infugem)	____/____/_____	☐
B31. Goserelin (Zoladex)	____/____/_____	☐
B32. Hexamethylmelamine (Hexalen)	____/____/_____	☐
B33. Ifosfamide (Ifex)	____/____/_____	☐
B34. Irinotecan (CPT-11, Camptosar)	____/____/_____	☐
B35. Larotrectinib (Vitrakvi)	____/____/_____	☐

Mode of Admin:
0 – Not given
1 – IV
2 – IP
3 – Both IV & IP
4 – Oral
5 – Oral & IV or IP
9 – Unknown

Systemic agents continued on next page

Systemic Therapy Agent	Date (mm/dd/yyyy)	Mode of Admin
B36. Letrozole (Femara)	___/___/_____	☐
B37. Leuprolide (Lupron)	___/___/_____	☐
B38. Megestrol acetate (Megace)	___/___/_____	☐
B39. Melphalan (Alkeran)	___/___/_____	☐
B40. Mirvetuximab Soravtansine-gynx (Elahere)	___/___/_____	☐
B41. Niraparib (Zejula)	___/___/_____	☐
B42. Olaparib (Lynparza)	___/___/_____	☐
B43. Paclitaxel (Taxol)	___/___/_____	☐
B44. Pembrolizumab (Keytruda)	___/___/_____	☐
B45. Pemetrexed (Alimta)	___/___/_____	☐
B46. Rucaparib (Rubraca)	___/___/_____	☐
B47. Tamoxifen (Nolvadex)	___/___/_____	☐
B48. Thiotepa (Tepadina)	___/___/_____	☐
B49. Topotecan (Hycamtin)	___/___/_____	☐
B50. Vinorelbine (Navelbine)	___/___/_____	☐
B51. Other, Specify _____	___/___/_____	☐
B52. Other, Specify _____	___/___/_____	☐
B53. Other, Specify _____	___/___/_____	☐

Mode of Admin:
0 – Not given
1 – IV
2 – IP
3 – Both IV & IP
4 – Oral
5 – Oral & IV or IP
9 – Unknown

Coding Info

Abstractor ID
☐☐☐☐☐

Date Abstracted
___/___/_____
mm dd yyyy

List all co-morbids on next page

Notes

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Abstractor's questions, problems or comments. Attach pages and documentation as needed.

Notes

POC 2021 DATA ACQUISITION MANUAL

APPENDIX A

Overall Patterns of Care Study

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POC 2021 DATA ACQUISITION MANUAL

APPENDIX B

PHYSICIAN VERIFICATION FORMS

Patterns of Care Study 2021 Diagnosis Year
Physician Verification Form

Patient Name _____

Patient Identification No. _____Physician_____

Date of Initial Diagnosis _____Type of Cancer Prostate Cancer

PLEASE DESCRIBE ALL CANCER THERAPY GIVEN TO THE PATIENT, REGARDLESS OF WHERE, WHEN OR BY WHOM THE THERAPY WAS ADMINISTERED. If you did not see this patient, please go to question #12.

1. Did the patient receive **ACTIVE SURVEILLANCE OR WATCHFUL WAITING/EXPECTANT MANAGEMENT** as first line therapy after diagnosis? (circle one)

   Yes, active surveillance Yes, watchful waiting/expectant management No

   Patient/Guardian Refused AS/WW/EM Unknown

   If Yes, did ACTIVE SURVEILLANCE end? (circle one)

   Yes (Date of end_____/_____/_____) No

2. Did the patient receive **RADIATION** therapy to the **PRIMARY SITE** at any time after diagnosis? (circle one)

   Yes (Date_____/_____/_____) No Patient/Guardian Refused Unknown

3. Did this patient receive any **SYSTEMIC THERAPY AGENTS?**
   _____Yes (Please mark all that apply in Q.4)
   _____Patient/Guardian refused ALL systemic therapy (Skip to Q.6)
   _____No (Skip to Q.6)
   _____Unknown (Skip to Q.6)

4. Please indicate whether each of the agents listed below was given, the date first administered if it was given, and whether the patient/guardian refused the agent if it was recommended.

Systemic Agent and Date		Circle if not given	Circle if refused
Abiraterone acetate (Zytiga, Yonsa)	Yes (Date____/____/_____)	No	Patient/guardian refused
Niraparib plus abiraterone (Akeega)	Yes (Date____/____/_____)	No	Patient/guardian refused
Aminoglutethimide (Cytadren)	Yes (Date____/____/_____)	No	Patient/guardian refused
Apalutamide (Erleada)	Yes (Date____/____/_____)	No	Patient/guardian refused
Bicalutamide (Casodex)	Yes (Date____/____/_____)	No	Patient/guardian refused
Bisphosphonate	Yes (Date____/____/_____)	No	Patient/guardian refused
Cabazitaxel (Jevtana)	Yes (Date____/____/_____)	No	Patient/guardian refused
Darolutamide (Nubeqa)	Yes (Date____/____/_____)	No	Patient/guardian refused
Degarelix (Firmagon)	Yes (Date____/____/_____)	No	Patient/guardian refused
Docetaxel (Taxotere)	Yes (Date____/____/_____)	No	Patient/guardian refused
Enzalutamide (Xtandi)	Yes (Date____/____/_____)	No	Patient/guardian refused
Estramustine (Emcyt)	Yes (Date____/____/_____)	No	Patient/guardian refused
Estrogens not otherwise specified	Yes (Date____/____/_____)	No	Patient/guardian refused
Finasteride (Proscar)	Yes (Date____/____/_____)	No	Patient/guardian refused

Flutamide (Eulexin)	Yes (Date____/____/_____)	No	Patient/guardian refused
Goserelin (Zoladex)	Yes (Date____/____/_____)	No	Patient/guardian refused
Ketoconazole (Nizoral)	Yes (Date____/____/_____)	No	Patient/guardian refused
Leuprolide (Lupron)	Yes (Date____/____/_____)	No	Patient/guardian refused
Lutetium Lu 177 vipivotide tetraxetan infusion (Pluvicto)	Yes (Date____/____/_____)	No	Patient/guardian refused
Mitoxantrone (Novantrone)	Yes (Date____/____/_____)	No	Patient/guardian refused
Nilutamide (Nilandron)	Yes (Date____/____/_____)	No	Patient/guardian refused
Olaparib (Lynparza)	Yes (Date____/____/_____)	No	Patient/guardian refused
Prednisone / Steroids not otherwise specified	Yes (Date____/____/_____)	No	Patient/guardian refused
Radium-223 infusion (Xofigo)	Yes (Date____/____/_____)	No	Patient/guardian refused
Relugolix (Orgovyx)	Yes (Date____/____/_____)	No	Patient/guardian refused
Rucaparib (Rubraca)	Yes (Date____/____/_____)	No	Patient/guardian refused
Sipuleucel-T (Provenge)	Yes (Date____/____/_____)	No	Patient/guardian refused
Talazoparib (Talzenna)	Yes (Date____/____/_____)	No	Patient/guardian refused
Other, specify 1 _____	Yes (Date____/____/_____)	No	Patient/guardian refused
Other, specify 2 _____	Yes (Date____/____/_____)	No	Patient/guardian refused
Other, specify 3 _____	Yes (Date____/____/_____)	No	Patient/guardian refused

5. Date of Final Systemic Therapy Administration Date____/____/_____ ____Unknown

6. Was this patient actively enrolled in an active/open clinical trial? ____Yes ____No (Skip to Q.8)

7. Please provide the name of the clinical trial sponsor and the clinical trial number.
   Sponsor (example: SWOG)_____
   Number (example: 8711)_____

8. Was the patient tested for and found to be positive for the following genetic mutations:

Mutation	**Tested (circle one)**	**Positive (Circle one)**
MSI/Microsatellite instability	Yes No	Yes No
MMR deficiency/Mismatch repair deficiency	Yes No	Yes No
BRCA1	Yes No	Yes No
BRCA2	Yes No	Yes No
ATM	Yes No	Yes No
PALB2	Yes No	Yes No
FANCA	Yes No	Yes No
RAD51D	Yes No	Yes No

Patterns of Care Study 2021 Diagnosis Year
Physician Verification Form

Mutation	Tested (circle one)	Positive (Circle one)
CHEK2	Yes No	Yes No
CDK12	Yes No	Yes No
Circulating tumor DNA (ctDNA)	Yes No	Yes No

9. Did this patient receive (check all that apply): ____ Palliative care → Type_____
____ Hospice care
____ Counseling/mental health svcs **after cancer dx**

10. Was the patient diagnosed with COVID-19 following cancer dx? ____ Yes → 1st pos test date _____
____ No

11. Did the COVID-19 pandemic impact the patient's care?

Type of Treatment	Impact of COVID-19 (C-19) on Cancer Treatment (Check One per Row)			
	Patient did not receive this tx OR no impact of C-19	Delayed, altered, or canceled treatment due to C-19	Patient refused this treatment due to C-19	Other impact of C-19 on this treatment
Primary site surgery	☐	☐	☐	☐
Primary site radiation	☐	☐	☐	☐
System therapy (any)	☐	☐	☐	☐
Palliative care	☐	☐	☐	☐

12. Did this patient experience a metastasis or recurrence AFTER diagnosis? ____Yes ____No

If Yes, date metastasis or recurrence identified: _/_____/_____

13. If you believe this information to be incomplete, are there other physicians we could contact who may have further information on this patient?

Dr._____ Address _____

_____

Dr._____ Address _____

_____

Comments: _____

_____

Signature_____ Date _____

Title/Role of person in the practice completing this form: _____

THANK YOU FOR YOUR HELP WITH THIS IMPORTANT STUDY.

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Patterns of Care Study 2021 Diagnosis Year
Physician Verification Form

Patient Name _____

Patient Identification No. _____Physician_____

Date of Initial Diagnosis _____Type of Cancer Ovarian Cancer

PLEASE DESCRIBE ALL CANCER THERAPY GIVEN TO THE PATIENT, REGARDLESS OF WHERE, WHEN OR BY WHOM THE THERAPY WAS ADMINISTERED. If you did not see this patient, please go to question #12.

1. Did the patient receive **RADIATION** therapy to the **PRIMARY SITE** at any time after diagnosis? (circle one)

   Yes (Date_____/_____/_____) No Patient/Guardian Refused Unknown

2. Did this patient receive any **SYSTEMIC THERAPY AGENTS?**
   _____Yes (Please mark all that apply in Q.3)
   _____Patient/Guardian refused ALL systemic therapy (Skip to Q.5)
   _____No (Skip to Q.5)
   _____Unknown (Skip to Q.5)

3. Please indicate whether each of the agents listed below was given, the date first administered if it was given, and whether the patient/guardian refused the agent if it was recommended. **If given**, please record the mode or modes of administration in the last column.

Systemic Agent and Date		Circle if not given	Circle if refused	Circle Mode(s) of Administration
Albumin bound paclitaxel (nab-paclitaxel, Abraxane)	Yes (Date____/____/_____)	No	Patient/ guardian refused	Oral IP Parenteral Unknown
Altretamine (Hexalen)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Anastrozole (Arimidex)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Bevacizumab (Alymsys, Avastin, Mvasi, Zirabev)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Capecitabine (Xeloda)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Carboplatin (Paraplatin)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Cisplatin (Platinol)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Cyclophosphamide (Cytoxan)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Docetaxel (Taxotere)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Doxorubicin (Adriamycin)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Doxorubicin Hydrochloride Liposome (Doxil, Lipodox 50)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Entrectinib (Rozlytrek)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Etoposide (VP16)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Exemestane (Aromasin)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown
Gemcitabine (Gemzar, Infugem)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral IP Parenteral Unknown

Patterns of Care Study 2021 Diagnosis Year
Physician Verification Form

Systemic Agent and Date		Circle if not given	Circle if refused	Circle Mode(s) of Administration
Goserelin (Zoladex)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Hexamethylmelamine (Hexalen)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Ifosfamide (Ifex)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Irinotecan (CPT-11, Camptosar)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Larotrectinib (Vitrakvi)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Letrozole (Femara)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Leuprolide (Lupron)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Megestrol acetate (Megace)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Melphalan (Alkeran)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Mirvetuximab Soravtansine-gynx (Elahere)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Niraparib (Zejula)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Olaparib (Lynparza)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Paclitaxel (Taxol)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Pembrolizumab (Keytruda)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Pemetrexed (Alimta)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Rucaparib (Rubraca)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Tamoxifen (Nolvadex)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Thiotepa (Tepadina)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Topotecan (Hycamtin)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Vinorelbine (Navelbine)	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Other, specify 1 _____	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Other, specify 2 _____	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown
Other, specify 3 _____	Yes (Date____/____/_____)	No	Patient/guardian refused	Oral Parenteral IP Unknown

4. Date of Final Systemic Therapy Administration Date____/____/_____ ____Unknown

5. Was this patient actively enrolled in an active/open clinical trial? ____Yes ____No (Skip to Q.7)

6. Please provide the name of the clinical trial sponsor and the clinical trial number.
   Sponsor (example: SWOG)_____
   Number (example: 8711)_____

7. Was the patient tested for and found to be positive for the following genetic mutations:

Mutation	**Tested (circle one)**	**Positive (Circle one)**
MSI/Microsatellite instability	Yes No	Yes No
MMR deficiency/Mismatch repair deficiency	Yes No	Yes No
BRCA1	Yes No	Yes No
BRCA2	Yes No	Yes No
Homologous recombination deficiency (HRD)	Yes No	Yes No
p53	Yes No	Yes No
PAX8	Yes No	Yes No
PDL-1	Yes No	Yes No
Circulating tumor DNA (ctDNA)	Yes No	Yes No

8. Did the patient receive any of these **AFTER DX?** (check all that apply):
   ____ Palliative care → Type_____
   ____ Hospice care
   ____ Counseling/mental health svcs

9. Was the patient diagnosed with COVID-19 **after cancer dx**?
   ____ Yes → 1st pos test date _____
   ____ No

10. Did the COVID-19 pandemic impact the patient's care?

Type of Treatment	**Impact of COVID-19 (C-19) on Cancer Treatment (Check One per Row)**			
	Patient did not receive this tx OR no impact of C-19	Delayed, altered, or canceled treatment due to C-19	Patient refused this treatment due to C-19	Other impact of C-19 on this treatment
Primary site surgery	☐	☐	☐	☐
Primary site radiation	☐	☐	☐	☐
System therapy (any)	☐	☐	☐	☐
Palliative care	☐	☐	☐	☐

11. Did this patient experience a **non-peritoneal** metastasis or recurrence **AFTER** dx? ____Yes ____No

If Yes→ date dx____/____/_____

12. Did this patient experience **peritoneal** metastasis or carcinomatosis **AFTER** dx? ____Yes ____No

    If Yes→ date dx____/____/_____

13. If you believe this information to be incomplete, are there other physicians we could contact who may have further information on this patient?

    Dr._____ Address _____

    _____

    Dr._____ Address _____

    _____

    Comments: _____

    _____

    Signature_____ Date _____

    Title/Role of person in the practice completing this form: _____

THANK YOU FOR YOUR HELP WITH THIS IMPORTANT STUDY.