Chapter 4: First Course of Therapy

Treatment or therapy for cancer should modify, control, remove, or destroy cancer tissue (cancer-directed treatment). Therapy can be used to treat cancer tissue in a primary or metastatic site(s), regardless of the patient's response to that treatment. The first course of therapy should include all cancer-directed treatments indicated in the initial treatment plan and delivered to the patient after the initial diagnosis of cancer. Multiple modalities of treatment may be included, and therapy may include regimens of a year or more. WCRS requires facilities to report the first course therapy/ treatment provided at that facility or any other facility if the information is available in the medical chart.

The treatment plan specifies the types of cancer-directed therapies proposed to eliminate or control the patient’s disease. Treatment intentions may be found in discharge summaries, consultations, and outpatient records. All cancer-directed therapies (surgery, radiation, chemotherapy, hormone therapy, immunotherapy, transplant/endocrine or other therapy) documented in the physician treatment plan and administered are considered first-course therapy.

Note 1: Make sure you enter first-course treatment only in the standard software treatment fields. Do not report subsequent treatment (for a class 32, as an example) in those fields. Subsequent treatment can be 1) recorded in the treatment text fields or 2) entered in specific second course treatment fields that your software vendor may make available to you. (WCRS Abstract Plus software does not have any subsequent or second-course treatment fields.)

Note 2: Surgical diagnostic and staging procedures such as biopsies, thoracentesis, and bypasses do not modify or destroy cancer cells. Surgical procedures that aspirate, biopsy or remove regional lymph nodes to diagnose and/or stage disease are to be entered in Scope of Regional Lymph Node Surgery, not in the Primary Site Surgery field.

Site-specific surgery codes are available in the Standards for Oncology Registry Entry (STORE) manual, Appendix B: https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/store_manual_2018 (Use the bookmark feature to quickly move to the appendix.)

The SEER RX web site contains drug classifications by specific treatment category (hormone, chemotherapy, etc.): http://seer.cancer.gov/seertools/seerrx/.
Definitions

**First course of therapy:** All treatments administered to the patient after the original diagnosis of cancer in an attempt to **destroy or modify the cancer tissue.**

**Active surveillance:** A treatment plan that involves closely watching a patient’s condition but not giving any treatment unless there are changes in test results that show the condition is getting worse. Active surveillance may be used to avoid or delay the need for treatments such as radiation therapy or surgery, which can cause side effects or other problems.

**Concurrent therapy:** A treatment that is given at the same time as another.

*Example:* Chemotherapy and radiation therapy

**Hospice:** A program that provides special care for people who are near the end of life and for their families, either at home, in freestanding facilities, or within hospitals. Hospice care may include treatment that destroys or modifies cancer tissue. If performed as part of the first course, treatment that destroys or modifies cancer tissue is collected when given in a hospice setting. “Hospice, NOS” is not specific enough to be included as first course treatment.

**Neoadjuvant therapy:** Systemic therapy or radiation therapy given prior to surgery to shrink the tumor.

**Palliative treatment:** The World Health Organization describes palliative care as treatment that improves the quality of life by preventing or relieving suffering.

*Note 1:* Palliative therapy is **part of the first course of therapy only** when it **destroys or modifies cancer tissue.**

*Example:* The patient was diagnosed with stage IV cancer of the prostate with painful bone metastases. The patient starts radiation treatment intended to shrink the tumor in the bone and relieve the intense pain. The radiation treatments are palliative because they relieve the bone pain; the radiation is also first course of therapy because it destroys proliferating cancer tissue.

*Note 2:* Procedures performed to palliate or alleviate symptoms may include surgery, radiation, systemic therapy and/or other pain management therapy; types of therapy that can also be considered first–course, cancer-directed treatment in other situations. If the therapy is used for palliative purposes only, the palliative treatment itself is NOT reportable to WCRS (but the case still is reportable - refer to Chapter 1 for rules on reportable case determination, if necessary).
**Watchful waiting:** Closely watching a patient’s condition but not giving treatment unless symptoms appear or change. Watchful waiting is sometimes used in conditions that progress slowly. It is also used when the risks of treatment are greater than the possible benefits. During watchful waiting, patients may be given certain tests and exams. Watchful waiting is sometimes used in prostate cancer. It is a type of expectant management.

**No treatment:** No treatment is considered a treatment option and may represent the first course of therapy. Reason for no treatment should be entered in the appropriate treatment field.

**If there is no treatment plan and:**

a. No other treatment guidelines are established, evaluate the therapy and the time it began in relation to the diagnosis date. If the therapy is a part of an established protocol or within accepted guidelines for the disease, consider it part of the first course of therapy.

b. No established protocol or management guidelines are established, and no physician counsel is available, use the following principle: *initial treatment must begin within four months of the date of initial diagnosis.*
New WCRS Required Data Field for 2018: Phase 1 Radiation Treatment Modality

Radiation modality reflects whether a treatment was external beam, brachytherapy, a radioisotope as well as their major subtypes, or a combination of modalities. This data item should be used to indicate the radiation modality administered during the first phase of radiation.

The first phase may be commonly referred to as an initial plan and a subsequent phase may be referred to as a boost or cone down, and would be recorded as Phase II, Phase III, etc. accordingly.

Coding Instructions

- Radiation treatment modality will typically be found in the radiation oncologist’s summary letter for the first course of treatment.

- For purposes of this data item, photons, x-rays and gamma-rays are equivalent.

- Use code 13 - Radioisotopes, NOS for radioembolization procedures, e.g. intravascular Yttrium-90.

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Treatment Timing

Use the following instructions in hierarchical order.

1. Use the documented first course of therapy (treatment plan) from the medical record. First course of therapy ends when the treatment plan is completed no matter how long it takes to complete the plan.

   Example: Hormonal therapy (e.g., Tamoxifen) after surgery, radiation, and chemotherapy. First course ends when hormonal therapy is completed, even if this takes years, unless there is documentation of disease progression, recurrence, or treatment failure (see #2 below).

2. First course of therapy ends when there is documentation of disease progression, recurrence, or treatment failure.

   Example 1: The documented treatment plan for sarcoma is pre-operative (neoadjuvant) chemotherapy, followed by surgery, then radiation or chemotherapy depending upon the pathology from surgery. Scans show the tumor is not regressing after pre-operative chemotherapy. Plans for surgery are cancelled, radiation was not administered, and a different type of chemotherapy is started. Code only the first chemotherapy as first course. Do not code the second chemotherapy as first course because it is administered after documented treatment failure.

   Example 2: The documented treatment plan for a patient with locally advanced breast cancer includes mastectomy, chemotherapy, radiation to the chest wall and axilla, and hormone therapy. The patient has the mastectomy and completes chemotherapy. During the course of radiation therapy, the liver enzymes are rising. Workup proves liver metastases. The physician stops the radiation and does not continue with hormone therapy (the treatment plan is altered). The patient is placed on a clinical trial to receive Herceptin for metastatic breast cancer. Code the mastectomy, chemotherapy, and radiation as first course of treatment. Do not code the Herceptin as first course of therapy because it is administered after documented disease progression.

When there is no documentation of a treatment plan or progression, recurrence or a treatment failure, first course of therapy ends one year after the date of diagnosis. Any treatment given after one year is second course of therapy in the absence of a documented treatment plan or a standard of treatment.
General Instructions - Treatment Coding for Solid Tumors

1. Code all treatment fields to 0 or 00 (Not done) when the physician opts for active surveillance. When the disease progresses or the patient becomes symptomatic, any prescribed treatment is second course.

   **Note:** Code Treatment Status (RX Summ--Treatment Status) to 2.

2. Code the treatment as first course of therapy if the patient refuses treatment but changes his/her mind and the prescribed treatment is implemented less than one year from the date of diagnosis, AND there is no evidence of disease progression.

3. The first course of therapy is no treatment when the patient refuses all treatment. Code all treatment fields to Refused.

   **Note:** Keep the refused codes even if the patient later changes his/her mind and decides to have the prescribed treatment.

   a. More than one year after diagnosis, or
   
   b. When there is evidence of disease progression before treatment is implemented

4. Code all treatment that was started and administered, whether completed or not. Document treatment discontinuation in text fields.

   **Example:** The patient completed only the first dose of a planned 30-day chemotherapy regimen. Code chemotherapy as administered.

5. Code the treatment on each abstract when a patient has multiple primaries and the treatment given for one primary also affects/treats another primary

   **Example 1:** The patient had prostate and bladder cancer. The bladder cancer was treated with a TURB. The prostate cancer was treated with radiation to the prostate and pelvis. The pelvic radiation includes the regional lymph nodes for the bladder. Code the radiation as treatment for both the bladder and prostate cases.
**Example 2:** The patient had a hysterectomy for ovarian cancer. The pathology report reveals a previously unsuspected microinvasive cancer of the cervix. Code the hysterectomy as surgical treatment for both the ovarian and cervix primaries.

6. Code the treatments only for the site that is affected when a patient has multiple primaries and the treatment affects only one of the primaries.

   **Example:** The patient has colon and tonsil primaries. The colon cancer is treated with a hemicolectomy and the tonsil primary is treated with radiation to the tonsil and regional nodes. Do not code the radiation for the colon. Do not code the hemicolectomy for the tonsil.

7. Code the treatment given as first course even if the correct primary is identified later when a patient is diagnosed with an unknown primary.

   **Example 1:** The patient is diagnosed with metastatic carcinoma, unknown primary site. After a full course of chemotherapy, the primary site is identified as prostate. Code the chemotherapy as first course of treatment.

   **Note:** Do not code treatment added to the plan when the primary site is discovered as first course. This is a change in the treatment plan.

   **Example 2:** The patient is diagnosed with metastatic carcinoma, unknown primary site. After a full course of chemotherapy, the primary site is identified as prostate. Hormonal treatment is started. Code the chemotherapy as first course of treatment. The hormone therapy is second course because it was not part of the initial treatment plan.
General Instructions - Treatment Coding for Hematopoietic Neoplasms

Some treatments for reportable hematopoietic diseases, such as transfusions, phlebotomy, and aspirin administration, do not meet the usual standard criteria for and definition of definitive treatment. Please refer to the SEER Hematopoietic and Lymphoid Neoplasm Database to look up the appropriate reportable treatments for these diseases. The website lists the standard treatments on each disease page: http://seer.cancer.gov/seertools/hemelymph/.

First Course of Treatment for Hematopoietic Neoplasms

Treatment varies by the type of hematopoietic neoplasm. Lymphomas can be treated with surgery (extranodal or nodal), chemotherapy, and radiation, while leukemias are often treated with chemotherapy and bone marrow transplants. In addition, immunotherapy (biologic response modifiers) and hormones are frequently used to treat hematopoietic neoplasms. Also, for many of these diseases, the principal treatment is either supportive care, observation, or another type of treatment that does not meet the usual definition of treatment that “modifies, controls, removes or destroys proliferating cancer tissue.”


Coding Instructions for Hematopoietic Neoplasms

1. When there is only one neoplasm (one primary), use the documented first course of therapy (treatment plan) from the medical record. First course of therapy ends when the treatment plan is completed, no matter how long it takes to complete the plan.

2. Chronic neoplasm followed by an acute neoplasm.
   a. The presence/absence of treatment DOES NOT affect the number of primaries when a chronic neoplasm transforms to an acute neoplasm.

Example: Patient diagnosed in 2000 with follicular lymphoma. Patient refused treatment. Patient returns in 2014 with DLBCL. Abstract the DLBCL as a second primary even though there was no treatment for the follicular lymphoma.
b. First course of treatment for the chronic neoplasm may or may not be completed when the chronic neoplasm transforms to the acute neoplasm.

3. Acute neoplasm followed by a chronic neoplasm.

   a. The presence/absence of treatment **DOES** impact the determination of the number of primaries when the acute neoplasm reverts to a chronic neoplasm (see Rules M12 and M13).

   b. The planned first course of therapy may not have been completed when a biopsy/pathologic specimen shows only chronic neoplasm after an initial diagnosis of an acute neoplasm.

   c. The patient may have completed the first course of treatment and have been cancer free (clinically, no evidence of the acute neoplasm) for an interim when diagnosed with the chronic neoplasm.

   d. The patient may not have been cancer free, but completed the first course of treatment and biopsy/pathology shows only chronic neoplasm.

Code the treatment on both abstracts when a patient has multiple primaries and the treatment given for one primary also affects/treats the other primary.

**Example:** Patient is diagnosed in May 2014 with both multiple myeloma (9732/3) and mantle cell lymphoma (9673/3), which are separate primaries per rule M15. The oncologist states she began Velcade chemotherapy for the lymphoma. Velcade would affect both primaries, so it should be coded on both abstracts.

**Leukemia**

For patients with a diagnosis of leukemia, the first course of therapy includes all cancer-directed treatments and planned therapies during or after the initial diagnosis of leukemia. All remission-inducing or maintenance cancer-directed therapy is recorded as the first course, including radiation to the central nervous system. The multiple modalities of therapy for the treatment of leukemia may involve a year or more.
**Example 1:** If the patient has an adverse reaction, the regimen may be changed and a new drug introduced. If the new chemotherapy drug(s) is in the same group as the initial therapy (anti-metabolite, alkylating agent, etc.) it is considered continuation of the first course of treatment. If the drug(s) is not in the same group, it is no longer the first course of therapy. Additionally, if the patient fails to respond to treatment and the regimen is changed, it is no longer first course of treatment.

**Example 2:** Physician plans a combination regimen of chemotherapy. Velban is one of the drugs but, due to adverse reactions, it is replaced with Oncovin after several cycles. The treatment continues as first course of therapy because Oncovin and Velban are both alkaloids. Conversely, if Velban had been replaced with Fludara, it is no longer first-course therapy because Fludara is an anti-metabolite.

**Example 3:** Physician plans a regimen of Adriamycin/Cytoxan. The patient does not respond and disease progresses so the treatment plan is changed to Methotrexate/SFU. The treatment becomes subsequent (and no longer reportable to WCRS) because the planned first course of treatment failed.

**Reporting Phlebotomy, Blood-Thinners/Anti-Clotting Medications, and Transfusions as Other Therapy**

- Do not collect **blood transfusions** (whole blood, platelets, etc.) as treatment. Blood transfusions are widely used to treat anemia and it is not possible to collect this procedure in a meaningful way.

- Collect **phlebotomy** for polycythemia vera (9950/3) ONLY.

- Collect **blood-thinners** and/or **anti-clotting agents** for essential thrombocythemia (9962/3) ONLY.

**Donor Leukocyte Infusions**

The use of donor leukocyte infusions for treatment of hematopoietic neoplasms, specifically leukemia’s, is increasing. Abstract as immunotherapy when a reportable hematopoietic neoplasm is treated with donor leukocyte infusion, even if it is not listed in the treatment section of the Hematopoietic database for the specific neoplasm.