Sentara Health Plans

Medicare

Chemotherapy and Supportive Care, Medical 316

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Coverage Policy	Medical 316
Version	10

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details*.

Description of Item or Service:

This policy addresses any oncology treatment that is not addressed in a specific medical necessity policy. This includes, but is not limited to chemotherapy, immunotherapy, supportive agents, CAR-T, and any newly approved therapeutic treatments used in oncology. Further, the approval criteria defined below applies to any requested use for drugs with a specific medical necessity policy if the policy doesn't address the patient specific scenario of the requested treatment.

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability as outlined below.

Clinical Indications and Criteria:

Sentara Health Plans follows a hierarchical process for reviewing utilization requests. The hierarchy varies depending upon the line of business. Unless otherwise noted, the review criteria used by Sentara Health Plans to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to **ONE or more of the following:**

- The medication request meets **ALL of the following:**
  - Ordered by a physician and administered by a provider properly licensed or certified to provide the therapy service (i.e., oncology specialty);
  - Drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA) meeting **ALL of the following:**
    - The dose and frequency is consistent with FDA labeling, NCCN, or indication-specific peer-reviewed literature, and if applicable or necessary, age and weight conditions are met;
    - If a-biomarker/genetic component is required per the FDA label, all genetic mutation, receptor, biomarker, laboratory work-up using an FDA-approved test (including both the results and name of test) has been completed;
    - If not indicated as a first line agent, previous therapies have been tried and failed as recommended by the FDA approved package insert or nationally recognized compendia;
    - In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were)

discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal);
    - If the brand formulation of any therapy with generic availability is requested, the provider must submit documentation to confirm treatment failure, contraindication or intolerance to the generic product;
- Drugs or regimens may be used off-label (without FDA support) and considered medically necessary if supported by any of the following compendia below and not listed as unsupported, not indicated, or not recommended within any compendia below must meet **ONE or more of the following:**
    - National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 2B
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Merative Micromedex DrugDex® (Class I, IIa, or IIb)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other uses of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals meets **ALL of the following:**
    - Article is from either American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; JAMA Oncology, The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; New England Journal of Medicine: Evidence, Radiation Oncology
    - Article is not a Meeting abstracts and case reports as they are excluded from consideration. Non-standard protocols may be approved based on unique clinical circumstances
- For reauthorization/continuation of therapy, all indication-specific and dosing conditions outlined above must be met as evidenced by **ALL of the following:**
    - Ordered by a physician and administered by a provider properly licensed or certified to provide the therapy service (i.e., oncology specialty);
    - Drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA) **ALL of the following:**
        - The dose and frequency is consistent with FDA labeling, NCCN, or indication-specific peer-reviewed literature, and if applicable or necessary, age and weight conditions are met;
        - If a biomarker/genetic component is required per the FDA label, all genetic mutation, receptor, biomarker, laboratory work-up using an FDA-approved test (including both the results and name of test) has been completed;
        - If not indicated as a first line agent, previous therapies have been tried and failed as recommended by the FDA approved package insert or nationally recognized compendia;
        - In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal);
        - If the brand formulation of any therapy with generic availability is requested, the provider must submit documentation to confirm treatment failure, contraindication or intolerance to the generic product;
    - The member must not be experiencing disease progression or unacceptable toxicity on the same agent/treatment or during treatment with another drug from the same drug class in a prior line of therapy (preclusion allowed with literature support for use beyond progression in a different combination)

Where applicable to coverage, chemotherapy administration is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to the following:

- The majority of the medical community does not support the use of the drug, device, medical treatment or procedure); or

- The use of this drug, device, medical treatment or procedure may have been shown to be unsafe and/or of no or questionable use as reported by current scientific literature and/or regulatory agencies; or
- The research regarding this drug, device, medical treatment or procedure may be so limited that an evaluation of safety and efficacy cannot be made; or
- The drug or device is not approved for marketing by the Food and Drug Administration (FDA); or
- The drug, device, or medical treatment is approved as Category B Non-Experimental/Investigational by the FDA

Document History:

Revised Dates:

- March 2025 – Updated language and criteria

Reviewed Dates:

- 2026: May – Implementation date of September 1, 2026. No change to current criteria. Updated version and references only.
- 2025: Implementation date of August 1, 2025. No change to criteria. Updated references.
- 2024: May – no changes references updated
- 2023: May
- 2022: May
- 2021: May
- 2020: July

Origination Date: October 2019

Coding Information:

Medically necessary with criteria:

Coding	Description
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump

96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)
96420	Chemotherapy administration, intra-arterial; push technique
96422	Chemotherapy administration, intra-arterial; infusion technique, up to 1 hour
96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure)
96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump
96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture
96542	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents
96549	Unlisted chemotherapy procedure

Considered Not Medically Necessary:

Coding	Description
	None

The preceding codes for treatments and procedures applicable to this policy are included above for informational purposes only. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy.

Special Notes: *

- Coverage- See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products - Policy is applicable to Sentara Health Plan Medicare products.
- Authorization requirements – Precertification by the plan is required. Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability as outlined above.
- Accelerated Approvals:
    - Ongoing | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals
    - Verified Clinical Benefit | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals
    - Withdrawn | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals
        - Individuals currently receiving treatment for a withdrawn indication should consult with their healthcare provider to determine if they should remain on therapy.
    - Continued determination of medical necessity for treatment of a withdrawn indication will be considered if the patient is established on therapy prior to the withdrawal date on the FDA Website.

- Special Notes: Additional Disclaimers:
    - Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, “Off-Label Use of Anti-Cancer Drugs and Biologics.” This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. Sentara Health Plans reserves the right to request medical documentation as needed to validate medical necessity determinations. Additionally, Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals and §80.5.9 National Coverage Determinations (NCDs). If National Coverage Determination (NCD) and/or Local Coverage Determinations (LCDs) exists, compliance with these policies is required where applicable (reference site: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.)
    - ~~o~~ Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. his Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine.
    - Medicare:
        - This medical policy expresses Sentara Health Plan’s determination of medically necessity of services, and they are based upon a review of currently available clinical information. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
        - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health

care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

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Keywords:

SHP Chemotherapy Administration, SHP Medical316, cancer