CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

General Oncology Drugs

Version: 1.0

EFFECTIVE DATE: 1/1/2024

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Please note the following:

General Oncology Drugs

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

General Oncology Drugs: Discussion

Chemotherapy is a general term that is often shortened to chemo. It is used to describe any treatment that attacks growing cells. Growth requires that cells divide to make new cells. These new cells replace and add to the cells that body parts are made of. Cancer cells grow when they shouldn't. Chemotherapy is given to interfere with dividing cancer cells. If it is successful, cancer cells will die faster than they grow, and the cancer will shrink. [1,2]

There are many different types of chemotherapy drugs used to treat cancer. They are given either alone or in combination with other drugs or treatments. These drugs are very different in their chemical composition, how they are prescribed and given, how useful they are in treating certain types of cancer, and the side effects they might have. The way the chemotherapy gets into the body is called the route of administration, which can be oral or parenteral. Oral means by mouth. Parenteral means not by mouth but rather injected directly. Many times, they are dripped or injected into a vein (given IV). IV chemotherapy can be given into a small vein, using a small plastic tube, or catheter, to be used for a few days. Chemotherapy can also be given using a larger tube, sometimes called a port, put into a big vein, intended for your whole course of IV treatments. Some chemotherapy can be given just under the skin (subcutaneous, or subQ). Some chemo can be put directly into the organ with cancer, such as your bladder (intravesical) or abdomen (intraperitoneal). [2]

The various oncology therapy types include alkylating agents, antimetabolites, anti-tumor antibiotics, topoisomerase inhibitors, mitotic inhibitors, corticosteroids, targeted therapy, hormone therapy, and immunotherapy.

Alkylating agents keep the cell from reproducing by damaging its DNA. These drugs work in all phases of the cell cycle and are used to treat many different cancers, including cancers of the lung, breast, and ovary as well as leukemia, lymphoma, Hodgkin disease, multiple myeloma, and sarcoma.

Antimetabolites interfere with DNA and RNA by acting as a substitute for the normal building blocks of RNA and DNA.

Topoisomerase inhibitors and mitotic inhibitors are called plant alkaloids. Topoisomerase inhibitors interfere with enzymes that separate the strands of DNA so they can be copied. Mitotic inhibitors work by stopping the cells from dividing to form new cells but can damage cells in all phases by keeping enzymes from making proteins that are needed for cell reproduction.

Targeted therapies work by finding specific proteins or receptors that some cancer cells have. The receptor is precisely targeted by the drug and normal cells are not affected by the drug(s).

Immunotherapy uses drugs to boost or alter a person's immune system. These drugs help a patient's immune system recognize and attack cancer cells.[1]

Requests are addressed by NantHealth's individual drug clinical policy guidelines. It is recognized that there may be requests that are not addressed in a named drug policy. For those requests, a clinical review may be conducted on a case-by-case basis utilizing criteria based on applicable endorsing agencies.

General Oncology Drugs: Definitions

- **Food and Drug Administration (FDA) -** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN) -** An alliance of 32 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Oncology Drug -** Any drug (chemotherapy, hormone therapy, gene therapy, biological therapy, or other drug) that is used to treat a cancer diagnosis.

General Oncology Drugs: Policy

General oncology drugs will be considered for coverage when the following criteria are met:

Multiple Disease Indications

Coverage of the requested drug must follow:

1. FDA-approved indications; AND/OR
2. NCCN guidelines category 1, 2A, OR 2B; AND
3. Prescribed by or in consultation with an oncologist; AND

4. At least 18 years of age unless indicated by the endorsing agencies (E.g., FDA or NCCN)

The below list of drugs is not an all-inclusive list and may be subject to additions or deletions throughout the annual review cycle as deemed by the endorsing agencies.

1. acalabrutinib
2. afatinib dimaleate
3. alectinib HCL
4. alpelisib
5. cobimetinib fumarate
6. dasatinib
7. decitabine
8. doxorubicin HCL liposomal
9. elacestrant hydrochloride
10. enasidenib mesylate
11. etoposide
12. fedratinib HCL
13. futibatinib
14. gefitinib
15. gilteritinib fumarate
16. idelalisib
17. imiquimod
18. isatuximab-irfc
19. ixabepilone
20. lanreotide acetate
21. mechlorethamine HCL (topical)
22. megestrol acetate
23. melphalan
24. melphalan HCL
25. mercaptopurine
26. midostaurin
27. octreotide acetate
28. olutasidenib
29. omacetaxine mepesuccinate
30. osimertinib mesylate
31. pacritinib citrate
32. pemigatinib
33. quizartinib
34. rasburicase
35. romidepsin
36. ropeginterferon alfa-2b-njft
37. siltuximab
38. sipuleucel-T
39. telotristat etiprate
40. temozolomide

41. temsirolimus
42. tocilizumab
43. topotecan HCL
44. valrubicin

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

General Oncology Drugs: References

1. How Chemotherapy Drugs Work. American Cancer Society. https://www.cancer.org/cancer/managing-cancer/treatment-types/chemotherapy/how-chemotherapy-drugs-work.html. Accessed August 1, 2023.
2. American Cancer Society Chemotherapy (What is Chemotherapy? | Chemo Treatment for Cancer) (https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html)
3. NCCN Guidelines Treatment by Cancer Type. https://www.nccn.org/guidelines/category_1. Accessed July 10, 2023.
4. Drugs@FDA: FDA-Approved Drugs. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed July 10, 2023.

General Oncology Drugs: Coding (CPT®, ICD 10 and HCPCS) *

* Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C18.9	Malignant neoplasm of colon, unspecified
C34.90	Malignant neoplasm of unspecified part of unspecified lung
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C61.0	Malignant neoplasm of the prostate

C81.9	Hodgkin lymphoma, unspecified
C85.9	Non-Hodgkin lymphoma, unspecified
J0893/J0894	decitabine
J1930/J1932	lanreotide acetate
J2353/J2354/J8499	octreotide acetate
J2783	rasburicase
J2860	siltuximab
J3262	tocilizumab
J8499/J8999	telotristat etiprate
J8560/J9181	etoposide IV and oral
J8565	gefitinib
J8600	melphalan
J8700/J9328	temozolomide
J8705/J9351	topotecan hydrochloride (HCL)
J8999	acalabrutinib, afatinib dimaleate, alectinib HCL, alpelisib, dasatinib, enasidenib maleate, fedratinib HCL, futibatinib, gilteritinib fumarate, idelalisib, imiquimod, midostaurin, olutasidenib, osimertinib mesylate, pacritinib citrate, pemigatinib, quizartinib
J8999/ C9399	cobimetinib fumarate
J8999/J9999/S0179	megestrol acetate
J8999/S0108	mercaptopurine
J9207	ixabepilone
J9227	isatuximab-irfc

J9245/J9246	melphalan HCL
J9262	omacetaxine mepesuccinate
J9318/J9319	romidepsin
J9330	temsirolimus
J9357	valrubicin
J9999	mechlorethamine hydrochloride (Topical), ropeginterferon alfa-2b-njft
Q2043	sipuleucel-T
Q2050	doxorubicin HCL liposomal

General Oncology Drug Policy: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	8/8/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	8/30/2023
6	Revision Changes:	