selecthealth

MEDICAL POLICY

INFUSED, INJECTED, INTRAVENOUS ONCOLOGY DRUGS AND SUPPORTIVE DRUGS FOR NEUTROPENIA AND ANEMIA

Policy # 999

Implementation Date:	7/1/20
Review Dates:	1/21/20
Revision Dates:	5/13/20

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS), and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

This document addresses oncology drugs and chemotherapy supportive drugs for neutropenia and anemia, which may include cytotoxic chemotherapy, biologic agents, immunotherapy, and other targeted therapies used to treat cancer. These treatments may be given by subcutaneous injection, intramuscular injection, or by intravenous infusion. Chemotherapy may be utilized as an adjunct to local treatment (neoadjuvant, adjuvant), primary treatment in both the curative and palliative setting, or as a radiosensitizing agent when used in conjunction with radiation.

This policy addresses both FDA-labeled indications and the supported off-label use of these cancer treatment options. The United States (U.S.) Food and Drug Administration (FDA) approves drugs for specific use(s) that are listed in the drug's product information label. Accepted off-label use based on Category 1 or 2A designation found in the most recent edition of the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (NCCN Compendium) or NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines).

Unless otherwise stated, authorization quantities are limited to FDA recommended dose. Dosing and administration schedule for different regimens should be adjusted and refined based on individual factors such as age, end-organ function, comorbidity, and/or toxicity.

Commercial Plan Policy

SelectHealth covers infused, injected, intravenous oncology drugs and supportive drugs for neutropenia and anemia when prior authorization guidelines have been met including the following:

1. The drug is approved by the FDA and being prescribed within the FDA indication including the approved line of therapy and combination of other therapy if applicable.; **OR** Accepted off-label use based on Category 1 or 2A designation found in the most recent edition of NCCN, NCCN Compendium, or NCCN Guidelines
2. The drug is being used in the FDA or NCCN supported clinical disease state and is supported by the clinical situation, such as the stage of disease, prior treatment, performance status, comorbid conditions, absence of contraindications, etc.
3. The individual has not experienced 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 UNLESS there is medical literature supporting use beyond progression in a different combination.

Continuation of an oncology agent/treatment is considered medically necessary if all of the following criteria are met:

1. The individual has not experienced disease progression or unacceptable toxicity while receiving or following treatment with the same regimen.
2. The individual's treatment has not exceeded label- or supported off-label-recommended quantity or timeframe limits.

Preferred oncology treatment biosimilars do not require prior authorization. All pegfilgrastim products and reference brand filgrastim (Neupogen) require prior authorization. Requirements for non-preferred biosimilars, reference brands and reference brand reformulations are as follows:

Avastin – Intolerance or contraindication to Mvasi and Zirabev

Herceptin – Intolerance or contraindication to Ogivri and Trazimera

Herceptin Hylecta – Intolerance or contraindication to Ogivri and Trazimera

Herzuma – Intolerance or contraindication to Ogivri and Trazimera

Kanjinti – Intolerance or contraindication to Ogivri and Trazimera

Ontruzant – Intolerance or contraindication to Ogivri and Trazimera

Rituxan – Intolerance or contraindication to Ruxience and Truxima

Rituxan Hycela – Intolerance or contraindication to Ruxience and Truxima

Neupogen – Intolerance or contraindication to Granix and Nivestym

Zarxio – Intolerance or contraindication to Granix and Nivestym

Leukine – Intolerance or contraindication to Granix and Nivestym

Neulasta – Intolerance or contraindication to Fulphila and Udenyca

Neulasta Onpro – Intolerance or contraindication to Fulphila and Udenyca OR cannot use preferred product pre-filled syringes due to inability to return to clinic for injection AND no access to home health for administration. Self-injection or caregiver administered injection of pre-filled syringe should be considered if unable to return to clinic and home health service is not available.

Ziextenzo – Intolerance or contraindication to Fulphila and Udenyca

Epogen – Intolerance or contraindication to Retacrit

Procrit – Intolerance or contraindication to Retacrit

SelectHealth Advantage (Medicare/CMS) (Preauthorization Required?)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the SelectHealth Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SelectHealth Community Care (Medicaid/CHIP) (Preauthorization Required?)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the SelectHealth Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Cancer treatment is highly complex and individualized, and the variability of patient factors and preferences must be considered when formulating a treatment plan. The FDA approves drugs for specific use(s) that are listed in the drug's product information label. The drug label approved by the FDA is the official description of a drug product, including information regarding indications, appropriate population, side effects, instructions, and safety information. In the majority of clinical scenarios, an attempt should be made to adhere to the FDA labeled indication; however, in some cases, there are sufficient data to support "off-label" use of drugs in a treatment regimen. Off-label drug use needs to be supported by a Category 1 (based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate) or 2A (based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate) recommendation by NCCN.

Billing/Coding Information

A Healthcare Common Procedure Coding System (HCPCS) billed needs to be specific to the prescribed and administered drug. A specific National Drug Code (NDC) and the American Medical Association's Current Procedural Terminology (CPT) applicable for the administered drug also needs to be included.

Key References

1. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 10, 2019.
2.United States Food and Drug Administration (FDA). Drugs at FDA Glossary of Terms. Revised November 14, 2017. Available at: http://www.fda.gov/drugs/informationondrugs/ucm079436.htm. Accessed on January 10, 2019.