MEDICAL MUTUAL®

Drug Policy

Policy:	**201410-CC**	**Initial Effective Date: 04/28/2014** **Annual Review Date: 11/15/2018** **Last Revised Date: 03/21/2019**
Code(s):	**HCPCS Codes C9024, J3490†, J3590†, J9019, J9020, J9153, J9203, J9205, J9207, J9225, J9261, J9266, J9315, J9352, J9371, J9999†**	
SUBJECT:	**Oncology Medications*** • **Arranon® (nelarabine)** • **Erwinaze®(asparaginase Erwinia chrysanthemi)** • **Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk)** • **Istodax® (romidepsin)** • **Ixempra® (ixabepilone)** • **Marqibo® (vincristine liposomal)** • **Mylotarg® (gemtuzumab ozogamicin)** • **Nelarabine (generic for Arranon)** • **Oncaspar (pegaspargase)** • **Onivyde ® (Irinotecan liposomal)** • **Sylatron® (peginterferon alfa-2b)** • **Vantas (Histrelin implant)** • **Vyxeos™ (daunorubicin/cytarabine)** • **Yondelis®(trabectedin)**	

***As of 4/1/2019, the following drugs (Brand name and generic) have been removed from PA requirement: Adriamycin, azacytidine, Dacogen, decitabine, gemcitabine, Gemzar, oxaliplatin, Vidaza, Bendeka/Treanda and bendamustine.**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

DATA SOURCES

The following sources will be reviewed for the indication, dose, dosing interval, and number of cycles.

Primary: NCCN Guidelines® (NCCN Clinical Practice Guidelines in Oncology), NCCN Compendium® (NCCN Drugs & Biologics Compendium), and prescribing information.

Other Sources: Clinical Pharmacology (Gold Standard), Drugdex® Evaluations, AHFS Drug Information (CMS-approved Part B Compendia), published literature with positive outcomes data (primarily PubMed), and ClinicalTrials.gov registry

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THIS POLICY APPLIES TO:

All oncology products used to treat oncology conditions. This policy does not apply to products either used for supportive care (e.g., anti-emetics, Neupogen® (filgrastim), Procrit® or Epogen® (epoetin alfa)) purposes or oncology products used to manage non-oncology conditions. If an oncology product is being used to treat a non-oncology condition, the oncology product is approved, unless the client has adopted criteria that address non-oncology conditions.

ASSESS THE FOLLOWING

- Indication
- Dose
- Dosing interval and number of cycles
- Waste management: dosage units (vial/syringe size), NDC, number of units for dose

EXISTING USERS

Patients who are already started on a particular oncology regimen while using another health plan's (insurer's) coverage are not reviewed for indication, but may be assessed for the appropriate dose, dosing interval, number of cycles, and waste management. This includes patients who were already started on the medication(s) while using another health plan's coverage or who are already started on the medication(s) at the time Care Continuum begins administering coverage.

PROCESS FOR EVALUATION AND DATA COLLECTION

1) Obtain patient's diagnosis and other patient and physician demographics, drug names, NDC for each drug if possible, dose, dosing interval/frequency, number of cycles, anticipated duration of therapy with this drug regimen, and start date.

2) Determine if patient is receiving these drugs as part of an investigational study. If so, determine if client's benefit coverage includes investigational use if the patient is enrolled in a clinical study.
Review case with Care Continuum physician for further review and analysis and consultation with an expert as needed. If needed, also review with the client the information available on the use of requested drug(s) for the individual patient to determine if coverage can be authorized.

3) Review data source(s) listed above for indication, dose, dosing interval, and number of cycles.

Indication is for the cancer diagnosis given and is not evaluated for whether it is appropriate at the patient's current disease stage. That is, the appropriate sequencing of therapy is not evaluated. The indication for drug therapy may require companion diagnostic (genetic) testing (e.g., Erbitux® (cetuximab) or Vectibix® (panitumumab) for "wild type" KRAS mutational status in metastatic colorectal cancer). Other Care Continuum policies adopted by the health plan may require that a generic product be used rather than a brand product. Also the health plan may utilize Care Continuum Medical Step Management or other policies that include oncology medications.

The dose and dosing interval may be adjusted due to adverse effects or changes in renal or hepatic function. These doses and interval changes may not be noted in the data sources, but should be considered when evaluating the dose and interval.

If the primary source(s) listed above has the information required, then further research in the other sources is not required. If the primary source does not have the information required for assessment, then Clinical

Pharmacology, Drugdex® Evaluations, and AHFS Drug Information are reviewed. PubMed is searched if these sources do not have the information needed. ClinicalTrials.gov is searched for investigation protocols if needed to determine if the trial is registered with this data base.

4) Waste management. The dose is calculated and the number of vials/syringes needed to provide the dose is assessed. Determine appropriate number of dosage units (vials, syringes) for pre-certification. Provider should indicate the NDC for each drug. If the dose changes, re-evaluate number of vials/syringes needed.

5) If the nurse reviewer is unable to approve the indication, dose, dosing interval, number of cycles, or vial size, forward case to medical director for formal review. The prescribing physician may provide information to consider for further review such as a protocol approved by an investigational review board (IRB), abstracts from scientific meetings, etc.

Documentation Requirements:

The Company reserves the right to request additional documentation and to deny reimbursement when it has determined that the services performed were not medically necessary, investigational and/or a pattern of practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes
HCPCS Codes C9024, J3490†, J3590†, J9017, J9019, J9020, J9153, J9203, J9205, J9207, J9225, J9261, J9266, J9315, J9352, J9371, J9999†

†When *unclassified drug* (J3490), *unclassified biologic* (J3590) and *not otherwise classified, antineoplastic drugs* (J9999) are determined to be one of the oncology medications listed within this policy.

NOTE: The process for evaluation and data collection identified in this policy will be followed for the oncology medications listed above.

HCPCS Code(s):

C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine (Vyxeos)
J3490	Unclassified drugs
J3590	Unclassified biologics
J9019	Injection, asparaginase (erwinaze), 1,000 iu
J9020	Injection, asparaginase, not otherwise specified, 10,000 units
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine (Effective 1/1/2019)

J9203	Injection, gemtuzumab ozogamicin, 0.1 mg (Mylotarg)
J9205	Injection, irinotecan liposome, 1 mg
J9207	Injection, ixabepilone, 1 mg
J9225	Histrelin implant, 50mg (Vantas)
J9261	Injection, nelarabine, 50 mg
J9266	Injection, pegaspargase, per single dose vial
J9315	Injection, romidepsin, 1 mg
J9352	Injection, trabectedin, 0.1 mg
J9371	injection, vincristine sulfate liposome, 1mg
J9999	Not otherwise classified, antineoplastic drugs