Pharmacy Policy

Antineoplastic Agents

Policy Number: 9.700
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth- MCO
	☒ MassHealth- ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Daurismo™ (glasdegib tablet)
- Erleada™ (apalutamide tablet)
- Farydak® (panobinostat capsule)
- Folotyn® (pralatrexate injection)
- Gleostine™ (lomustine capsule)
- Idhifa® (enasidenib mesylate tablet)
- Lonsurf® (tipiracil hcl and trifluridine tablet)
- Lynparza™ (olaparib capsule, and tablets)
- Ninlaro® (ixazomib capsule)
- Odomzo® (sonidegib capsules)
- Pomalyst® (pomalidomide capsule)
- Rubraca™ (rucaparib tablets)
- Tazverik™ (tazemetostat tablet)
- Talzenna® (talazoparib capsule)
- Tibsovo® (ivosidenib tablet)
- Valchlor™ (mechlorethamine gel)
- Zejula™ (niraparib capsules)
- Zelboraf® (vemurafenib tablet)
- Zytiga® (abiraterone acetate tablet)

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	• FDA approved indication
	• Use supported by:
	  o American Hospital Formulary Service Drug Information
	  o DRUGDEX Information System
	  o United States Pharmacopeia- Drug Information
	  o National Comprehensive Cancer Network (categories 1,2a, and 2b)
	• Medically accepted indications will also be considered for approval.

Exclusion Criteria	• Experimental or Investigational Use • Being used in a clinical trial

Required Medical Information	Documentation of the following:
	
	1. A documented diagnosis for a medically accepted indication including:
	  • Use of a drug which is FDA-approved and that the quantity being prescribed is consistent with dosing listed in manufacture package labeling; OR
	  • Use of which is supported by one or more citations included or approved for inclusion in any of the compendia:
	  o American Hospital Formulary Service Drug Information
	  o DRUGDEX Information System
	  o United States Pharmacopeia-Drug Information (or its successor publications)
	  o National Comprehensive Cancer Network (categories 1, 2a, 2b only); AND
	
	2. Documentation of dose and dates of all previous therapies and the resulting outcomes. For example, NCCN guidelines 'preferred' regimens over 'other' regimens with evidence Category 1, 2a and 2b; AND
	3. Documentation that the proper succession of the therapies (as indicated in the FDA labeling or compendia) have been tried and failed (i.e. intolerance, contraindication, or progression; AND
	4. Chart notes detailing the member's current clinical status; AND
	5. Chart documentation and related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment.

Age Restrictions	None
Prescriber Restriction	Prescriber must be a specialist appropriate to the disease state being treated (e.g. oncologist, hematologist, etc…)

Coverage Duration	Initial and Re-authorization: Maximum of 12 months
Other criteria	Reauthorization: 1. The clinical condition has improved or stabilized (decreased progression) without treatment-related adverse events.

Clinical Background Information and References

1. Pomalyst® [package insert]. Summit (NJ): Celgene Corporation; Feb 2013.
2. NCCN Drugs & Biologics Compendium™ [database on the internet]. Fort Washington (PA): National Comprehensive Cancer Network; Updated periodically [cited 2014 Jun 24]. Available from http://www.nccn.org.
3. Folotyn® (package insert). Westminster (CO): Allos Therapeutics; Jan 2011.
4. Zelboraf® (package insert). San Francisco (CA): Genentech; Mar 2014.
5. Lynparza™ (package insert). Wimington (DE): AstraZeneca; Dec 2014.
6. Farydak® (package insert). East Hanover (NJ): Novartis; Feb 2015.
7. Lonsurf (trifluridine/tipiracil) [prescribing information]. Princeton, NJ: Taiho Oncology; September 2015.
8. Ninlaro (ixazomib) [prescribing information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; November 2015.
9. Valchlor (mechlorethamine) [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals; August 2015.
10. Tazverik (tazemetostat) [prescribing information]. Cambridge, MA: Epizyme, Inc.; January 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.041 Antineoplastic Agents Policy retired, new policy created	1/1/2021	P&T Committee

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Next Review Date

2021

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.