

Multiple Myeloma Agents
Effective 07/31/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Darzalex, Empliciti, Kyprolis and Sarclisa are only available through the Medical Benefit.		

Overview

No PA	Drugs that require PA
bortezomib ^{MB}	Blenrep® (belantamab mafodotin-blmf)
Thalomid® (thalidomide)	Darzalex® (daratumumab) ^{MB}
Velcade® (bortezomib) ^{MB}	Darzalex Faspro® (daratumumab-hyaluronidase-fihj) ^{MB}
	Empliciti® (elotuzumab) ^{MB}
	Kyprolis® (carfilzomib) ^{MB}
	Ninlaro® (ixazomib)
	Pomalyst® (pomalidomide)
	Sarclisa® (isatuximab-irfc) ^{MB}
	Xpovio® (selinexor)

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Blenrep® (belantamab mafodotin-blmf)

ALL of the following:

1. Diagnosis of multiple myeloma
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing

4. Member has received at least **FOUR** prior chemotherapy regimens **OR** contraindication to the use of recommended chemotherapy regimens
5. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following proteasome inhibitors: bortezomib, Kyprolis® (carfilzomib), Ninlaro® (ixazomib), and Velcade® (bortezomib)
6. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following immunomodulatory agents: Pomalyst® (pomalidomide), Revlimid® (lenalidomide), and Thalomid® (thalidomide)
7. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following anti-CD38 monoclonal antibodies: Darzalex® (daratumumab), Darzalex Faspro® (daratumumab-hyaluronidase-fihj), and Sarclisa® (isatuximab-irfc)

Documentation of prior treatments with listed agents above (criteria 5-7) is sufficient to meet approval criteria, regardless of clinical response.

Darzalex® (daratumumab)

Darzalex Faspro® (daratumumab hyaluronidase-fihj)

ALL of the following:

1. Diagnosis of multiple myeloma (monotherapy)
 - a. Agent will be used as monotherapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing (For Darzalex® (daratumumab): weight is required)
 - d. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
 - i. bortezomib
 - ii. Kyprolis® (carfilzomib)
 - iii. Ninlaro® (ixazomib)
 - iv. Velcade® (bortezomib)
 - e. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following immunomodulatory agents:
 - i. Pomalyst® (pomalidomide)
 - ii. Revlimid® (lenalidomide)
 - iii. Thalomid® (thalidomide)
 - f. **ONE** of the following:
 - i. Paid claims within the past 30 days or physician attestation of inadequate response or adverse reaction to **ONE** proteasome inhibitor and **ONE** immunomodulatory agent noted above
 - ii. History of a total of **THREE** trials with chemotherapy regimens for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)

Documentation of prior treatments with listed agents above (criteria d.-e.) is sufficient to meet approval criteria, regardless of clinical response.

2. Diagnosis of multiple myeloma (combination therapy)
 - a. Agent will be used as part of combination therapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing (For Darzalex® (daratumumab): weight required)
 - d. **ONE** of the following:
 - i. **ALL** of the following:
 1. Member is newly diagnosed and ineligible for transplant
 2. **ONE** of the following:



- a. Requested agent will be used in combination with Revlimid® (lenalidomide) and dexamethasone
- b. Requested agent will be used in combination with Velcade® (bortezomib) or bortezomib and melphalan and prednisone*
- 3. Clinical rationale for use of the requested combination instead of Velcade® (bortezomib) or bortezomib and Revlimid® (lenalidomide) and dexamethasone
- ii. **BOTH** of the following:
 - 1. Member is newly diagnosed and eligible for transplant
 - 2. Requested agent will be used in combination with Velcade® (bortezomib) or bortezomib and thalidomide and dexamethasone†
- iii. **BOTH** of the following:
 - 1. Physician attestation of inadequate response or adverse reaction to at least one prior line of systemic therapy
 - 2. Requested agent will be used in combination with dexamethasone and at least one other agent for treatment of multiple myeloma (excluding anti-CD38 agents)

**The NCCN also recommends the use of Darzalex® (daratumumab) or Darzalex Faspro® (daratumumab-hyaluronidase-fihj) in combination with Velcade® (bortezomib) or bortezomib and cyclophosphamide and dexamethasone for this population; therefore, if a request for this combination meets all other criteria it may be approved.*

† The NCCN also recommends the use of Darzalex® (daratumumab) or Darzalex Faspro® (daratumumab-hyaluronidase-fihj) in combination with Velcade® (bortezomib) or bortezomib and cyclophosphamide and dexamethasone or in combination with Velcade® (bortezomib) or bortezomib and Revlimid® (lenalidomide) and dexamethasone for this population; therefore, if a request combination meets all other criteria it may be approved.

Darzalex Faspro® (daratumumab-hyaluronidase-fihj)

ALL of the following:

- 1. Diagnosis of light chain amyloidosis
- 2. Prescriber is an oncologist or hematologist
- 3. Appropriate dosing
- 4. Requested agent will be used in combination with Velcade® (bortezomib) or bortezomib and cyclophosphamide and dexamethasone

Empliciti® (elotuzumab)

ALL of the following:

- 1. Diagnosis of multiple myeloma
- 2. Prescriber is an oncologist or hematologist
- 3. Appropriate dosing (weight required)
- 4. **ONE** of the following:
 - a. **BOTH** of the following:
 - i. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** prior regimen for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
 - ii. Requested medication will be used in combination with Revlimid® (lenalidomide) and dexamethasone†
 - b. **ALL** of the following:



- i. Paid claims or physician attestation of inadequate response or adverse reaction to at least **TWO** prior regimens for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
- ii. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
 1. bortezomib
 2. Kyprolis® (carfilzomib)
 3. Ninlaro® (ixazomib)
 4. Velcade® (bortezomib)
- iii. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Revlimid® (lenalidomide)
- iv. Requested medication will be used in combination with Pomalyst® (pomalidomide) and dexamethasone

*†Empliciti® (elotuzumab) in combination with Velcade® (bortezomib) or bortezomib and dexamethasone is not an FDA-approved regimen; however, based on available data, the NCCN recommends this regimen as a treatment option for patients with relapsed or refractory multiple myeloma. If a request for this combination meets all other criteria (criteria 1 through 4a) and the prescriber documents clinical rationale for use of the requested combination instead of Empliciti® (elotuzumab) plus Revlimid® (lenalidomide) and dexamethasone, (e.g., inadequate response or adverse reaction to a Revlimid® [lenalidomide] containing regimen or contraindication to Revlimid® [lenalidomide]), it may be **approved**.*

Kyprolis® (carfilzomib)

ONE of the following:

1. Diagnosis of multiple myeloma (monotherapy)
 - a. Agent will be used as monotherapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing (height and weight OR BSA required)
 - d. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** prior chemotherapy regimen for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
2. Diagnosis of multiple myeloma (combination therapy)
 - a. Agent will be used as part of combination therapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing (height and weight OR BSA required)
 - d. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** prior chemotherapy regimen for the requested indication‡ (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
 - e. Requested medication will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors)

‡ If the request is for carfilzomib in combination with lenalidomide and dexamethasone or cyclophosphamide and dexamethasone member may be approved without prior chemotherapy if all other criteria are met AND prescriber documents rationale for use of the requested regimen instead of Velcade® (bortezomib) or bortezomib and Revlimid® (lenalidomide) and dexamethasone.

Ninlaro® (ixazomib)

ALL of the following:

1. Diagnosis of multiple myeloma
2. Prescriber is an oncologist or hematologist



3. Appropriate dosing
4. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** prior chemotherapy regimen for the requested indication* (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
5. Requested medication will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors)†
6. Quantity limit of ≤ 3 capsules for a 28-day supply

The NCCN recommends the use of Ninlaro® (ixazomib) in combination with Revlimid® (lenalidomide) and dexamethasone for first-line therapy in both transplant eligible and non-transplant candidates; therefore, requests for this combination may be **approved without previous trial if all other criteria is met. The NCCN recommends the use of Ninlaro® (ixazomib) in combination with cyclophosphamide and dexamethasone for first-line therapy in patients who are transplant eligible. If the prescriber documents that the request is for a transplant eligible patient and all other criteria are met the request may be **approved** without previous trial.*

*†Ninlaro® (ixazomib) is not FDA-approved for monotherapy; however, per the NCCN guideline this is recommended for maintenance therapy for patients following autologous stem cell transplant. If the prescriber documents that request is for maintenance therapy following transplant, monotherapy may be **approved**.*

Pomalyst® (pomalidomide)

ONE of the following:

1. Diagnosis of Multiple Myeloma
 - a. Prescriber is an oncologist or hematologist
 - b. Appropriate dosing
 - c. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following immunomodulatory agents:
 - i. Revlimid® (lenalidomide)
 - ii. Thalomid® (thalidomide)
 - d. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
 - i. bortezomib
 - ii. Kyprolis® (carfilzomib)
 - iii. Ninlaro® (ixazomib)
 - iv. Velcade® (bortezomib)

Documentation of prior treatments with listed agents above (criteria c.-d.) is sufficient to meet approval criteria, regardless of clinical response.

2. Diagnosis of Kaposi sarcoma
 - a. Prescriber is an oncologist or hematologist
 - b. Appropriate dosing
 - c. **ONE** of the following:
 - i. Member has acquired immunodeficiency syndrome (AIDS) and has failed highly active antiretroviral therapy
 - ii. Member is human immunodeficiency virus (HIV)-negative
 - d. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to pegylated liposomal doxorubicin and paclitaxel**

***Daunorubicin could be used in place of pegylated liposomal doxorubicin. If a member has a previous trial to daunorubicin, this criterion would be met.*

Sarclisa® (isatuximab-irfc)

ALL of the following:



1. Diagnosis of multiple myeloma
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing (weight required)
4. **ONE** of the following:
 - a. **BOTH** of the following:
 - i. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** chemotherapy regimen for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
 - ii. Requested agent will be used in combination with Kyprolis® (carfilzomib) and dexamethasone
 - b. **ALL** of the following:
 - i. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
 1. bortezomib
 2. Kyprolis® (carfilzomib)
 3. Ninlaro® (ixazomib)
 4. Velcade® (bortezomib)
 - ii. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Revlimid® (lenalidomide)
 - iii. History of a total of at least **TWO** trials with appropriate regimens for the requested indication (*refer to Appendix for list of chemotherapeutic agents that suffice for trials*)
 - iv. Requested agent will be used in combination with Pomalyst® (pomalidomide) and dexamethasone

Xpovio® (selinexor)

ONE of the following:

1. Diagnosis of multiple myeloma (monotherapy)
 - a. Agent will be used as monotherapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing
 - d. Member has received at least **FOUR** prior chemotherapy regimens **OR** contraindication to the use of recommended chemotherapy regimens
 - e. Inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following proteasome inhibitors: bortezomib, Kyprolis® (carfilzomib), Ninlaro® (ixazomib), Velcade® (bortezomib)
 - f. Inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following immunomodulatory agents: Pomalyst® (pomalidomide), Revlimid® (lenalidomide), Thalomid® (thalidomide)
 - g. Inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following anti-CD38 monoclonal antibodies: Darzalex® (daratumumab), Darzalex Faspro® (daratumumab-hyaluronidase-fihj), Sarclisa® (isatuximab-irfc)
 - h. Requested medication will be used in combination with dexamethasone

Documentation of prior treatments with listed agents above (criteria e.-g.) is sufficient to meet approval criteria, regardless of clinical response.
2. Diagnosis of multiple myeloma (combination therapy)
 - a. Agent will be used as part of combination therapy
 - b. Prescriber is an oncologist or hematologist
 - c. Appropriate dosing



- d. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** prior chemotherapy regimen for the requested indication
 - e. Requested agent will be used in combination with Velcade® (bortezomib) or bortezomib and dexamethasone*
3. Diagnosis of diffuse large B-cell lymphoma (DLBCL)
- a. Prescriber is an oncologist or hematologist
 - b. Appropriate dosing
 - c. Paid claims or physician attestation that member has received at least **TWO** prior chemotherapy regimens **OR** contraindication to the use of recommended chemotherapy regimens

* The NCCN also recommends the use of Xpovio® (selinexor) in combination with Darzalex® (daratumumab) or Darzalex Faspro® (daratumumab-hyaluronidase-fihj) and dexamethasone for this population or in combination with Pomalyst® (pomalidomide) and dexamethasone; therefore, if a request for one of these combinations meets all other criteria it may be approved.

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

- 1. Initial approvals will be granted for 6 months
- 2. Reauthorizations will be granted for 12 months
- 3. The following quantity limits apply:

Ninlaro 4 mg	3 capsules per 28 days
--------------	------------------------
- 4. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
- 5. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

Appendix

Chemotherapy Trials

Previous chemotherapy trials may include doxorubicin, liposomal doxorubicin and cyclophosphamide. Any of the aforementioned agents may be used as monotherapy or in combination with dexamethasone. Single-agent dexamethasone may also suffice as a previous chemotherapy trial. Although not currently recommended by the most updated version of the NCCN guidelines, members may have had trials with vincristine, etoposide, cisplatin and bendamustine in the past.

The following regimens are currently recommended by the NCCN guidelines:

Primary Myeloma Therapy

For transplant candidates:

- Preferred Regimens



- o Bortezomib/lenalidomide/dexamethasone (category 1)
- o Carfilzomib/lenalidomide/dexamethasone
- Other Recommended Regimens
 - o Daratumumab/lenalidomide/bortezomib/dexamethasone
- Useful in Certain Circumstances
 - o Bortezomib/doxorubicin/dexamethasone
 - o Bortezomib/thalidomide/dexamethasone (category 1)
 - o Bortezomib/cyclophosphamide/dexamethasone
 - o Carfilzomib/cyclophosphamide/dexamethasone
 - o Cyclophosphamide/lenalidomide/dexamethasone
 - o Daratumumab/bortezomib/thalidomide/dexamethasone
 - o Daratumumab/carfilzomib/lenalidomide/dexamethasone
 - o Daratumumab/cyclophosphamide/bortezomib/dexamethasone
 - o Ixazomib/cyclophosphamide/dexamethasone
 - o Ixazomib/lenalidomide/dexamethasone (category 2B)
 - o VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide/bortezomib)

For non-transplant candidates:

- Preferred Regimens
 - o Bortezomib/lenalidomide/dexamethasone (category 1)
 - o Daratumumab/lenalidomide/dexamethasone (category 1)
- Other Recommended Regimens
 - o Carfilzomib/lenalidomide/dexamethasone
 - o Daratumumab/bortezomib/melphalan/prednisone (category 1)
 - o Daratumumab/cyclophosphamide/bortezomib/dexamethasone
 - o Ixazomib/lenalidomide/dexamethasone
- Useful in Certain Circumstances
 - o Lenalidomide/low-dose dexamethasone (category 1)
 - o Bortezomib/cyclophosphamide/dexamethasone
 - o Bortezomib/dexamethasone
 - o Carfilzomib/cyclophosphamide/dexamethasone
 - o Cyclophosphamide/lenalidomide/dexamethasone

Maintenance Therapy

- Preferred Regimens
 - o Lenalidomide (category 1)
- Other Recommended Regimens
 - o Ixazomib (category 2B)
 - o Daratumumab o Bortezomib
- Useful in certain circumstances
 - o Bortezomib/lenalidomide ± dexamethasone
 - o Carfilzomib/lenalidomide

Therapy for Previously Treated Multiple Myeloma

- Preferred Regimens for Early Relapses (1–3 prior therapies)
 - o If relapse is >6 months, the regimen used for primary therapy may be repeated.
 - o Ixazomib/lenalidomide/dexamethasone (category 1)
 - o Bortezomib/lenalidomide/dexamethasone
 - o Bortezomib-Refractory



- Daratumumab/lenalidomide/dexamethasone (category 1)\
- Daratumumab/carfilzomib/dexamethasone (category 1)
- Carfilzomib/lenalidomide/dexamethasone (category 1)
- Isatuximab-irfc/carfilzomib/dexamethasone (category 1)
- Carfilzomib/pomalidomide/dexamethasone
 - After one prior therapy including lenalidomide and a PI
 - Daratumumab/pomalidomide/dexamethasone (category 1)
 - After two prior therapies including lenalidomide and a PI
 - Isatuximab-irfc/pomalidomide/dexamethasone (category 1)
 - After two prior therapies including an IMiD and a PI and with disease progression on/within 60 days of completion of last therapy
 - Ixazomib/pomalidomide/dexamethasone
- o Lenalidomide-Refractory
 - Daratumumab/carfilzomib/dexamethasone (category 1)
 - Daratumumab/bortezomib/dexamethasone (category 1)
 - Isatuximab-irfc/carfilzomib/dexamethasone (category 1)
 - Carfilzomib/pomalidomide/dexamethasone
 - After one prior therapy including lenalidomide and a PI
 - Daratumumab/pomalidomide/dexamethasone (category 1)
 - After two prior therapies including lenalidomide and a PI
 - Isatuximab-irfc/pomalidomide/dexamethasone (category 1)
 - After two prior therapies including an IMiD and a PI and with disease progression on/within 60 days of completion of last therapy
 - Pomalidomide/bortezomib/dexamethasone (category 1)
 - Ixazomib/pomalidomide/dexamethasone
- Other Recommended Regimens for Early Relapses (1–3 prior therapies)
 - o Bortezomib/liposomal doxorubicin/dexamethasone (category 1)
 - o Bortezomib/cyclophosphamide/dexamethasone
 - o Carfilzomib/cyclophosphamide/dexamethasone
 - o Carfilzomib (twice weekly)/dexamethasone (category 1)
 - o Cyclophosphamide/lenalidomide/dexamethasone
 - o Daratumumab/cyclophosphamide/bortezomib/dexamethasone
 - o Elotuzumab/bortezomib/dexamethasone
 - o Elotuzumab/lenalidomide/dexamethasone (category 1)
 - o Ixazomib/cyclophosphamide/dexamethasone
 - o Selinexor/bortezomib/dexamethasone (once weekly) (category 1)
 - o After two prior therapies including an IMiD and a PI and disease progression on/within 60 days of completion of last therapy
 - Pomalidomide/cyclophosphamide/dexamethasone
 - o After two prior therapies including lenalidomide and a PI
 - Elotuzumab/pomalidomide/dexamethasone
- Useful in Certain Circumstances for Early Relapses (1–3 prior therapies)
 - o Bortezomib/dexamethasone (category 1)
 - o Carfilzomib/cyclophosphamide/thalidomide/dexamethasone
 - o Carfilzomib (weekly)/dexamethasone
 - o Lenalidomide/dexamethasone (category 1)
 - o Venetoclax/dexamethasone only for t(11;14) patients
 - o Selinexor/daratumumab/dexamethasone
 - o Selinexor/carfilzomib/dexamethasone



- o After two prior therapies including IMiD and a PI and with disease progression on/within 60 days of completion of last therapy
 - Pomalidomide/dexamethasone (category 1)
 - Selinexor/pomalidomide/dexamethasone
- o For treatment of aggressive MM
 - DCEP (dexamethasone/cyclophosphamide/etoposide/cisplatin)
 - DT-PACE/VTD-PACE
(dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide ± bortezomib)
- o After at least three prior therapies including a PI and an IMiD or are double-refractory to a PI and an IMiD
 - Daratumumab
- Therapies for Patients with Late Relapses (>3 prior therapies)
 - o Bendamustine
 - o Bendamustine/bortezomib/dexamethasone
 - o Bendamustine/carfilzomib/dexamethasone
 - o Bendamustine/lenalidomide/dexamethasone
 - o High-dose or fractionated cyclophosphamide
 - o After at least four prior therapies, including an anti-CD38 monoclonal antibody, a PI, and an IMiD
 - Idecabtagene vicleucel
 - Ciltacabtagene autoleucel
 - Teclistamab-cqyv
 - Useful in certain circumstances:
 - Belantamab mafodotin-blmf (if available through compassionate use program)
 - o After at least four prior therapies and whose disease is refractory to at least two PIs, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody Selinexor/dexamethasone

References

1. Carfilzomib (Kyprolis). Briefing Document for Oncologic Drugs Advisory Committee Meeting: NDA 202714. Rockville (MD): Food and Drug Administration; 2012 Jun 20 [cited 2017 Jan 20]. Available from: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM308563.pdf>
2. Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Aug 10]. Available from: <http://www.utdol.com/utd/index.do>.
3. Darzalex® [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2021 Mar.
4. Empliciti® [package insert]. Princeton (NJ): Bristol-Myers Squibb; 2019 Oct.
5. Kyprolis® [package insert]. South San Francisco (CA): Onyx Pharmaceuticals Inc; 2021 Mar.
6. Ninlaro® [package insert]. Cambridge (MA): Takeda Pharmaceutical Company Limited; 2021 Mar.
7. Pomalyst® [package insert]. Summit (NJ): Celgene Corporation; 2020 Dec.
8. Xpovio® [package insert]. Newton (MA): Karyopharma Therapeutics; 2021 Apr.
9. Darzalex Faspro® (daratumumab-hyaluronidase-fihj) [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2021 Mar.
10. Sarclisa® [package insert]. Bridgewater (NJ): Sanofi-Aventis; 2021 Mar.
11. Blenrep® [package insert]. Bridgewater (NJ): Sanofi-Aventis; 2020 Aug.
12. Daratumumab Approved in Multiple Myeloma. The ASCO Post. 2015 Nov 25; Volume 6, Issue 21. Cited 2016 Dec 12. Available from: <http://www.ascopost.com/issues/november-25-2015/daratumumab-approved-in-multiple-myeloma/>.



13. Lokhorst HM, Plesner T, Laubach JP, Nahi H, Gimsing P, Hansson M, et al. Targeting CD38 with Daratumumab Monotherapy in Multiple Myeloma. *N Engl J Med*. 2015 Sep 24;373(13):1207-19.
14. Lonial S, Dimopoulos M, Palumbo A. Elotuzumab Therapy for Relapsed or Refractory Multiple Myeloma. *N Engl J Med* 2015; 373:621-63.
15. FDA approves Empliciti, a new immune-stimulating therapy to treat multiple myeloma [FDA News Release]. Food and Drug Administration. 2015 Nov 30 [cited 2017 Jan 20]. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm474684.htm>.
16. Velcade® [package insert]. Cambridge (MA): Millennium Pharmaceuticals Inc; 2019 Apr.
17. Siegel DS, Martin T, Wang M, Vij R, Jakubowiak AJ, Lonial S, et al. A phase 2 study of single-agent carfilzomib (PX-171-003-A1) in patients with relapsed and refractory multiple myeloma. *Blood*. 2012 Jul.
18. What is Ninlaro? [web page on the internet]. Multiple Myeloma Research Foundation. 2015 Dec 29 [cited 2016 Dec 12]. Available from: <https://www.themmr.org/multiple-myeloma-knowledge-center/myeloma-drugs-guide/ninlaro-ixazomib/>
19. U.S. FDA Approves Takeda's NINLARO® (ixazomib), the First and Only Oral Proteasome Inhibitor to Treat Multiple Myeloma [press release on the internet]. Cambridge (MA): Takeda Pharmaceuticals International Co; 2015 Nov 20 [cited 2016 Dec 12]. Available from: https://www.takeda.com/news/2015/20151121_7185.html.
20. Chustecka Z. Ixazomib in First Oral Triplet for Multiple Myeloma. *Medscape*. 2015 Dec 7 [cited 2016 Dec 12]. Available from: <http://www.medscape.com/viewarticle/862726>.
21. FDA approves Pomalyst for advanced multiple myeloma [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2013 Feb 8 [cited 2013 Feb 21]. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm338895.htm>
22. Lacy MQ, Tefferi A. Pomalidomide therapy for multiple myeloma and myelofibrosis: an update. *Leukemia and Lymphoma*. 2011 Apr;52(4):560-6.
23. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma Version 7.2021 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2021 Apr 26 [cited 2021 Aug 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.
24. Griffin PT, Ho VQ, Fulp W, Nishihori T, Shain KH, Alsina M, Baz RC. A comparison of salvage infusional chemotherapy regimens for recurrent/refractory multiple myeloma. *Cancer*. 2015 Oct 15;121(20):3622-30.
25. Gentile M, Vigna E, Recchia AG, Morabito L, Mendicino F, Giagnuolo G, Morabito F. Bendamustine in multiple myeloma. *Eur J Haematol*. 2015 Nov;95(5):377-88.
26. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Systemic Light Chain Amyloidosis Version 1.2022 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2021 Jun 29 [cited 2021 Aug 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.
27. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): B-Cell Lymphomas Version 4.2021 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2021 May 5 [cited 2021 Aug 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.

Review History

01/26/2022 - Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

07/12/2023 – Reviewed and updated for P&T. Darzalex Faspro and Sarclisa added to medical benefit with PA. Formatting for Blenrep and Xpovio updated to make verbiage consistent with other agents in the guideline, and “documentation of prior treatment with listed agents is sufficient to meet approval criteria, regardless of clinical



response” footnote was added to agents requiring prior trials with LCAs. Chemotherapy Trials section of appendix was updated to match latest NCCN recommendations. Added appendix for Brand/generic preferred verbiage. Effective 07/31/2023.

