

Carfilzomib (Kyprolis®)

Place of Service Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: J9047 per 1mg

Conditions listed in policy (see criteria for details)

- [Multiple myeloma, primary therapy](#)
- [Multiple myeloma, previously treated](#)
- [Multiple myeloma, maintenance therapy](#)
- [Systemic light chain amyloidosis](#)
- [Waldenstrom's macroglobulinemia / Lymphoplasmacytic lymphoma](#)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Proteasome inhibitor

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Kyprolis® (carfilzomib) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Multiple myeloma, primary therapy

1. Initial treatment, **AND**
2. Documentation of contraindication/intolerable side effects to Velcade (bortezomib), **AND**
3. **Effective 10/30/2023 and after**, will require one of the following:
 - Used in combination with Darzalex, lenalidomide, and dexamethasone, OR
 - Used in combination with cyclophosphamide and dexamethasone, OR
 - Used in combination with lenalidomide and dexamethasone

Covered Doses and Coverage Period

Kyprolis with daratumumab (Darzalex), lenalidomide and dexamethasone:

Covered Doses for 8 Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on day 1
- 56 mg/m² IV on days 8, 15

Cycle 2 – 8 (28-day cycle):

- 56 mg/m² IV on days 1, 8, 15

Kyprolis with cyclophosphamide and dexamethasone:

Covered Doses for 8 Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 56 mg/m² IV on days 8, 9, 15, 16

Cycles 2-8 (28-day cycle):

- 56 mg/m² IV on days 1, 2, 8, 9, 15, 16

Kyprolis with lenalidomide and dexamethasone:

Covered Doses for 7 Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 36 mg/m² IV on days 8, 9, 15, 16

Cycle 2-7:

- 36 mg/ m² IV on days 1, 2, 8, 9, 15, 16

ICD-10:

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

Multiple myeloma – previously treated

1. Previously treated disease, **AND**
2. One of the following:
 - a. Single agent therapy, **OR**
 - b. Combination therapy with one of the following:
 - i. Use with dexamethasone, or
 - ii. Use with lenalidomide and dexamethasone, or
 - iii. Use with daratumumab (Darzalex), lenalidomide, and dexamethasone, or
 - iv. Use with daratumumab (Darzalex) and dexamethasone, or
 - v. Use with daratumumab-hyaluronidase (Darzalex Faspro) and dexamethasone, or
 - vi. Use with cyclophosphamide and dexamethasone, with or without thalidomide, or
 - vii. Use with pomalidomide (Pomalyst) and dexamethasone, or
 - viii. Use with isatuximab-irfc (Sarclisa) and dexamethasone, or
 - ix. Use with selinexor (Xpovio) and dexamethasone, or
 - x. Use with bendamustine and dexamethasone and patient has received 3 or more prior therapies

Multiple Myeloma Therapy Classes

IMiDs (Immunomodulatory Drugs)	Proteasome Inhibitors	Chemotherapy
<ul style="list-style-type: none"> • Revlimid (lenalidomide) • Pomalyst (pomalidomide) • Thalomid (thalidomide) 	<ul style="list-style-type: none"> • Velcade (bortezomib) • Kyprolis (carfilzomib) • Ninlaro (ixazomib) 	<ul style="list-style-type: none"> • Doxil (doxorubicin HCl liposome injection) • Alkylator chemotherapy: Cytoxan (cyclophosphamide), Melphalan
Histone Deacetylase Inhibitor	Monoclonal Antibodies	BCL-2 inhibitor
<ul style="list-style-type: none"> • Farydak (panobinostat) 	<ul style="list-style-type: none"> • Darzalex (daratumumab) • Darzalex Faspro (daratumumab and hyaluronidase-fihj) • Emluciti (elotuzumab) • Sarclisa (isatuximab) 	<ul style="list-style-type: none"> • Vendexta (venetoclax)
Antibody-Drug Conjugate	Nuclear export inhibitor	CAR-T Cell Agent
<ul style="list-style-type: none"> • Blenrep (belantamab mafodotin-blmf) 	<ul style="list-style-type: none"> • Xpovio (selinexor) 	<ul style="list-style-type: none"> • Abecma (idecabtagene vicleuce) • Breyanzi - (lisocabtagene maraleuce)
Stem Cell Transplantation		
<ul style="list-style-type: none"> • High-dose chemotherapy and stem cell transplantation 		

Covered Doses and Coverage Period

Single agent Kyprolis or in combination with lenalidomide and dexamethasone:

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle)

- 20 mg/m² IV on days 1, 2
- 27 mg/ m² IV on days 8, 9, 15, 16

Cycle 2 – 12 (28-day cycle):

- 27 mg/ m² IV on days 1, 2, 8, 9, 15, 16

Cycle 13 – indefinite (28-day cycle):

- 27 mg/m² IV on days 1, 2, 15, 16

Kyprolis in combination with:

1. **dexamethasone**
2. **daratumumab (Darzalex) / daratumumab-hyaluronidase (Darzalex Faspro) and dexamethasone**

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on day 1
- 70 mg/m² IV on days 8, 15

Cycle 2 - indefinite (28-day cycle):

- 70 mg/m² IV on days 1, 8, 15

OR

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 56 mg/m² IV on days 8, 9, 15, 16

Cycle 2 -indefinite (28-day cycle):

- 56 mg/m² IV on days 1, 2, 8, 9, 15, 16

Kyprolis with cyclophosphamide and dexamethasone:

Covered Doses for 9 Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 36 mg/m² IV on days 8, 9, 15, 16

Cycles 2-9:

- 36 mg/m² IV on days 1, 2, 8, 9, 15, 16

Cycle 10 and after:

- Maintenance therapy can follow

Kyprolis with pomalidomide (Pomalyst) and dexamethasone:

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 27 mg/m² IV on days 8, 9, 15, 16

Cycles 2 – 6 (28-Day cycle):

- 27 mg/m² on days 1, 2, 8, 9, 15, 16

Cycles 7 - indefinite (28-Day cycle):

- 27 mg/m² on days 1, 2, 15, 16

Kyprolis in combination with isatuximab-irfc (Sarclisa) and dexamethasone

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
 - 56 mg/m² IV on days 8, 9, 15, 16
- Cycle 2 -indefinite (28-day cycle):
- 56 mg/m² IV on days 1, 2, 8, 9, 15, 16

Kyprolis with selinexor (Xpovio) and dexamethasone

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on day 1
- 56 mg/m² IV on days 8, 15

Cycles 2 – Indefinite (28-Day cycle):

- 56 mg/m² on days 1, 8, 15

Kyprolis with bendamustine and dexamethasone

Covered Doses for Indefinite Cycles

Cycle 1 (28-day cycle):

- 20 mg/m² IV on days 1, 2
- 27 mg/m² IV on days 8, 9, 15, 16

Cycles 2 – 8 (28-Day cycle):

- 27 mg/m² on days 1, 2, 8, 9, 15, 16

Cycles 9 - indefinite (28-Day cycle):

- 27 mg/m² on days 1, 2, 15, 16

ICD-10:

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

Multiple myeloma, maintenance therapy

1. Used in combination with lenalidomide, **AND**
2. Either of the following:
 - a. After response to primary treatment, or
 - b. After response or stable disease following a hematopoietic cell transplant

Covered Doses

Up to 36 mg/m² on days 1, 2, 15, 16 of a 28-day cycle

Coverage Period

Indefinite

ICD-10:

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

Systemic light chain amyloidosis

1. Disease is relapsed or refractory, **AND**
2. Either of the following:
 - a. Being used as a single agent, or
 - b. Being used in combination with dexamethasone

Covered Doses and Coverage Period

Cycle 1 (28-day cycle):

- 20 mg/m² IV on day 1
- 27 mg/m² IV on days 8, 15

Cycle 2 – Indefinite (28-day cycle):

- 56 mg/m² IV on days 1, 8, 15

ICD-10:

E85.81, E85.89, E85.9

Waldenstrom's macroglobulinemia (WM) / Lymphoplasmacytic Lymphoma

1. Used in combination with rituximab and dexamethasone, **AND**
2. Either of the following:
 - a. Used as primary therapy AND patient is unable to use a Velcade (bortezomib) regimen, OR
 - b. Used as retreatment of relapse after completion of primary treatment with Kyprolis

Covered Doses

Initial and Relapse

- Up to 36 mg/m² IV for 4 days per 21-day cycle for up to 6 cycles

Maintenance

- Up to 36 mg/m² IV for 2 days per cycle, given every 8 weeks for 8 cycles

Coverage Period

Initial and Relapse: Up to 6 cycles

Maintenance: Up to 8 cycles

ICD-10:

C83.00-C83.09, C88.0, Z85.72, Z85.79

3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Kyprolis® (carfilzomib) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

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(5) Additional Information

How supplied:

10 mg, 30 mg, 60 mg (Single-use vials)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Kyprolis® (carfilzomib) [Prescribing information]. South San Francisco, CA: Onyx Pharmaceuticals,

6/2022.

- National Comprehensive Cancer Network. Multiple Myeloma. (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Systemic light chain amyloidosis. (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Waldenstrom's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (Version 1.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- New indication in Section (2): Added coverage for maintenance therapy in multiple myeloma
Rationale: NCCN category 2A support
- Section (2): Multiple myeloma, primary therapy – **Effective 10/30/2023 and after**, will require combination use with one of the following regimens: 1) with daratumumab, lenalidomide, and dexamethasone; 2) with cyclophosphamide and dexamethasone; or 3) with lenalidomide and dexamethasone
Rationale: NCCN category 2A support
- Section (2): Multiple myeloma, previously treated –
 - Remove management for two prior therapies for coverage of Kyprolis in combination with Pomalyst and dexamethasone
 - Expand coverage for previously treated multiple myeloma to include combination use with the following regimens: 1) with bendamustine and dexamethasone for late relapse or progressive disease (>3 prior therapies); and 2) with Darzalex, lenalidomide, and dexamethasone
Rationale: NCCN category 1 support

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*