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JOHNS HOPKINS		Review Date	04/20/2022
MEDICINE	<u>Subject</u>	Revision Date	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: kyprolis

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I. POLICY

A. Kyprolis (carfilzomib) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

- A. Kyprolis may be approved for patients who meet the following:
 - 1. Multiple Myeloma
 - a. Documentation has been submitted showing the patient has symptomatic multiple myeloma
 - b. Documentation has been submitted showing one of the following:
 - I. Kyprolis will be used as primary therapy in one of the following regimens:
 - i. Combination therapy with lenalidomide and dexamethasone
 - ii. Combination therapy with cyclophosphamide and dexamethasone
 - II. Kyprolis will be used for treatment of relapsed or refractory disease in one of the following regimens after patients have had inadequate response to one or more lines of therapy:
 - i. Monotherapy
 - ii. Combination therapy with dexamethasone
 - iii. Combination therapy with lenalidomide and dexamethasone
 - iv. Combination therapy with cyclophosphamide and dexamethasone
 - v. Combination therapy with cyclophosphamide, thalidomide, and dexamethasone
 - vi. Combination therapy with daratumumab and dexamethasone
 - vii. Combination therapy with panobinostat (Farydak) in patients that have experienced inadequate response with at least two prior regimens, including bortezomib (Velcade) and an immunomodulatory agent
 - viii. Combination therapy with pomalidomide (Pomalyst) and dexamethasone in patients that have experienced inadequate response with at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor
 - ix. Combination therapy with isatuximab-irfc (Sarclisa) and dexamethasone
 - 2. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

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a. Documentation has been submitted supporting the patient's diagnosis, and showing Kyprolis will be used as a component of the CaRD (carfilzomib, rituximab, and dexamethasone) regimen.

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be limited to 12months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment.

IV. EXCLUSIONS

- A. Kyprolis will not be covered for the following:
 - 1. Any indications or uses that are not FDA-approved or guideline-supported

V. RECOMMENDED DOSAGE

- A. Please refer to the FDA-approved prescribing information, and clinical guidelines for indication-specific dosing details.
- B. For all indications, dosing does not exceed the following:
 - a. If using twice weekly: 56 mg/m2 (not to exceed 124 mg) per dose, not to exceed 6 doses per 28 days
 - b. If using once weekly: 70 mg/m2 (not to exceed 154 mg) per dose, not to exceed 3 doses per 28 days

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, carfilzomib, 1 mg	J9047

VII. REFERENCES

- 1. Kyprolis [prescribing information]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; November 2021.
- 2. The NCCN Drugs & Biologics Compendium 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 2,2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

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