DISCLAIMER

West Virginia Family Health medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

West Virginia Family Health provides coverage under the medical-surgical benefits of the Company’s Medicaid products for medically necessary intravenous infusions of Kyprolis (carfilzomib).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person’s unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and all applicable state and federal regulations.

DEFINITIONS

Multiple Myeloma (MM) – A cancer that forms in a type of white blood cell (plasma cell) in the bone marrow. Plasma cells help fight infections by making antibodies that recognize and attack germs. In patients with myeloma, the plasma cells form abnormal antibodies, which can damage the bone, bone marrow, and other organs.
**Kyprolis (carfilzomib)** – A proteasome inhibitor that exerts antiproliferative and proapoptotic activities to delay tumor growth.

**PROCEDURES**

1. Kyprolis is considered medically necessary as an intravenous infusion when the member meets the following criteria for multiple myeloma:
   A. The member is aged 18 years or older; AND
   B. The prescribing physician must be a Hematologist or Oncologist; AND
   C. Prophylaxis for herpes zoster is needed (notated in chart documentation); AND
   D. The drug will be used as monotherapy for the treatment of a member with relapsed or refractory multiple myeloma who has received one or more lines of therapy; OR
   E. The drug will be used in combination with dexamethasone or lenalidomide for the treatment of relapsed or refractory multiple myeloma if the disease was previously treated with one to three lines of prior therapy; OR
   F. The drug will be used in combination with dexamethasone or lenalidomide as primary treatment for relapsed/refractory multiple myeloma in stem cell transplant-eligible members who have received one to three lines of therapy and bortezomib-containing regimen is not suitable; AND
   G. Dosing is consistent with FDA-approved labeling:
      1) Initial dose of 20mg/m\(^2\) IV for two doses
      2) Maintenance dose of 27mg/m\(^2\) IV with subsequent cycles

2. Contraindications
   There are no known contraindications to Kyprolis.

3. When Kyprolis is not covered
   Kyprolis is not covered for conditions other than those listed above because the scientific evidence has not been established. Therefore, services are considered not medically necessary.

   Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and will be reviewed on a case-by-case basis to determine medical necessity.

   When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by West Virginia Family Health at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Kyprolis is outpatient.
GOVERNING BODIES APPROVAL
On July 20, 2012, the FDA approved Kyprolis to treat patients with advanced multiple myeloma who have received at least two prior therapies, including treatment with bortezomib and an immunomodulatory therapy.

On July 24, 2015, the FDA approved Kyprolis to treat patients with relapsed multiple myeloma with a combination of lenalidomide and dexamethasone who have received one to three prior lines of therapy.

On January 21, 2016, the FDA approved Kyprolis to treat patients with relapsed or refractory multiple myeloma with a combination of dexamethasone (monotherapy) or with lenalidomide plus dexamethasone who have received one to three lines of therapy.

CODING REQUIREMENTS

Covered Procedure Codes

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9047</td>
<td>Injection, carfilzomib, 1 mg</td>
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Covered Diagnosis Codes

<table>
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<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
<tr>
<td>C90.10</td>
<td>Plasma cell leukemia</td>
</tr>
<tr>
<td>C90.11</td>
<td>Plasma cell leukemia in remission</td>
</tr>
<tr>
<td>C90.12</td>
<td>Plasma cell leukemia in relapse</td>
</tr>
<tr>
<td>C90.20</td>
<td>Extramedullary plasmacytoma not having achieved remission</td>
</tr>
<tr>
<td>C90.21</td>
<td>Extramedullary plasmacytoma in remission</td>
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<tr>
<td>C90.22</td>
<td>Extramedullary plasmacytoma in relapse</td>
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<tr>
<td>C90.30</td>
<td>Solitary plasmacytoma not having achieved remission</td>
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<tr>
<td>C90.31</td>
<td>Solitary plasmacytoma in remission</td>
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<tr>
<td>C90.32</td>
<td>Solitary plasmacytoma in relapse</td>
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<tr>
<td>Z85.72</td>
<td>Personal history of non-Hodgkin lymphoma</td>
</tr>
<tr>
<td>Z85.79</td>
<td>Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues</td>
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REIMBURSEMENT

Participating facilities will be reimbursed per their West Virginia Family Health contract.
POLICY SOURCE(S)


- NCCN Guidelines Version 3.2017: Multiple Myeloma


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
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<tbody>
<tr>
<td>06/06/2017</td>
<td>Initial policy developed</td>
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<tr>
<td>09/12/2017</td>
<td>QI/UM Committee approval</td>
</tr>
<tr>
<td>11/01/2017</td>
<td>Provider effective date</td>
</tr>
</tbody>
</table>
ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call the number on the back of your ID card (TTY: 711).

ATENCION: Si usted habla español, servicios de asistencia lingüística, de forma gratuita, están disponibles para usted. Llame al número en la parte posterior de su tarjeta de identificación (TTY: 711).

请注意：如果您说中文，可向您提供免费语言协助服务。

请拨打您的身份证背面的号码（TTY：711）。

ATTENTION: Si c'est créole que vous connaissez, il y a un certain service de langues qui est gratuit et disponible pour vous-même. Composez le numéro qui est au dos de votre carte d'identité. (TTY: 711).

들먹: 한국어를 사용하시는 분들은 무료로 이용할 수 있습니다. ID 카드의 뒷면에 있는 번호로 전화해 주세요. (TTY: 711).

ATTENZIONE: se parla italiano, per lei sono disponibili servizi d'assistenza linguistica a titolo gratuito. Contatti il numero riportato sul retro della sua carta d'identità (TTY: 711).

일본어 사용하시는 분들은 무료로 이용할 수 있습니다. ID 카드 뒷면에 있는 번호로 전화해 주세요. (TTY: 711).

CHUYỂN: Nếu quý vị nói tiếng Việt, chúng tôi cung cấp dịch vụ hỗ trợ ngôn ngữ miễn phí cho quý vị. Xin gọi số điện thoại ở mặt sau thẻ ID của quý vị (TTY: 711).


ATTENSYON: Kung nagasalita ka ng Tagalog, may makukuha kang mga libreng serbisyo tulong sa wika. Tawagan ang numero sa likod ng iyong ID card (TTY: 711).

ध्वम हैं: यदि आप हिन्दी बोलते हैं, तो आपके लिए निर्देशित भाषा सहायता सेवा उपलब्ध है।

आपके सदस्य पहचान (ID) कोड के पीछे है एक नंबर पर फोन करें। (TTY: 711).

तोम fuqamat: ती लें एर्तु कोर्टबी, जन फ्रेंचलॉक स्मैस, एफ एफ एफ की ओर देविट बी लाई नामानुसार कार्ड की शंका पर अर्ज

तबी आ: अगर आप आर्थिक चीजों के साथ बाहर नहीं हैं, तो आपके लिए निर्देशित भाषा सहायता सेवा उपलब्ध है।

आपके सदस्य पहचान (ID) कोड के पीछे है एक नंबर पर फोन करें। (TTY: 711).

Aandacht: Indien u Nederlands spreekt, is de taaladviesdienst gratis beschikbaar voor u.

Bel het nummer op de achterkant van uw identificatie (ID) kaart (TTY: 711).

ВНИМАНИЕ: Если вы говорите по-русски, вы можете воспользоваться бесплатными услугами языковой поддержки. Позвоните по номеру, указанному на обороте вашей идентификационной карты (номер для текст-телефонных устройств (TTY: 711).

ATENÇÃO: Se a sua língua é o português, temos atendimento gratuito para você no seu idioma. Ligue para o número no verso da sua identidade (TTY: 711).


注: 日本語が母国語の方は言語アシスタント・サービスを無料でご利用いただけます。ID カードの裏に明記されている番号に電話をおかけてください(TTY: 711).

BAA ÁKONIN'NINA: Diné k’ehgo yônî “go, language assistance services, él’ t’áá nilk’eh, bee nikà a’doowol, él’ bee ná’ahóót’ii’”, ID bee nééhózingo nantiníih bine’Déé” (TTY: 711) jëh hodílinih.