

PA Criteria	Criteria Details																
<b>Description</b>	BLNREP is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate.																
<b>Covered Uses (FDA approved indication)</b>	BLNREP is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, in combination with bortezomib and dexamethasone, who have received at least two prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent).																
<b>Dosing and Administration</b>	<table border="1"> <thead> <tr> <th>Indication</th> <th>Dosing Regimen</th> </tr> </thead> <tbody> <tr> <td>Multiple Myeloma</td> <td> <p>2.5 mg/kg (using actual BW) IV infusion Q3 weeks for eight cycles (given with bortezomib + dexamethasone), followed by BLNREP 2.5 mg/kg Q3 weeks as a single agent.</p> <p>Continue until disease progression or unacceptable toxicity.</p> <p>Infuse each dose over 30 minutes.</p> </td> </tr> </tbody> </table>	Indication	Dosing Regimen	Multiple Myeloma	<p>2.5 mg/kg (using actual BW) IV infusion Q3 weeks for eight cycles (given with bortezomib + dexamethasone), followed by BLNREP 2.5 mg/kg Q3 weeks as a single agent.</p> <p>Continue until disease progression or unacceptable toxicity.</p> <p>Infuse each dose over 30 minutes.</p>												
Indication	Dosing Regimen																
Multiple Myeloma	<p>2.5 mg/kg (using actual BW) IV infusion Q3 weeks for eight cycles (given with bortezomib + dexamethasone), followed by BLNREP 2.5 mg/kg Q3 weeks as a single agent.</p> <p>Continue until disease progression or unacceptable toxicity.</p> <p>Infuse each dose over 30 minutes.</p>																
<b>Billing and Coding Information</b>	<table border="1"> <thead> <tr> <th>10-digit NDC</th> <th>11-digit NDC</th> </tr> </thead> <tbody> <tr> <td>0173-0913-01</td> <td>00173-0913-01</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>HCPCS Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>J9999</td> <td>Not otherwise classified, antineoplastic drugs</td> </tr> <tr> <td>J3590</td> <td>Unclassified biologics</td> </tr> <tr> <td>C9399</td> <td>Unclassified drugs or biologics</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>CPT Procedural Codes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>96413</td> <td>Chemotherapy IV infusion, up to 1 hour</td> </tr> </tbody> </table>	10-digit NDC	11-digit NDC	0173-0913-01	00173-0913-01	HCPCS Code	Description	J9999	Not otherwise classified, antineoplastic drugs	J3590	Unclassified biologics	C9399	Unclassified drugs or biologics	CPT Procedural Codes	Description	96413	Chemotherapy IV infusion, up to 1 hour
10-digit NDC	11-digit NDC																
0173-0913-01	00173-0913-01																
HCPCS Code	Description																
J9999	Not otherwise classified, antineoplastic drugs																
J3590	Unclassified biologics																
C9399	Unclassified drugs or biologics																
CPT Procedural Codes	Description																
96413	Chemotherapy IV infusion, up to 1 hour																
<b>Product Availability</b>	<i>Single-dose vial:</i> 70 mg lyophilized powder for reconstitution.																
<b>Contraindications</b>	None.																
<b>Recommended Medical Monitoring</b>	<p><b>BLACK BOX WARNING: Ocular Toxicity</b> – BLNREP causes changes in the corneal epithelium resulting in vision changes, including severe visual impairment and symptoms, such as blurred vision and dry eyes. In clinical studies, corneal ulcers, including cases with infection, also occurred.</p> <ol style="list-style-type: none"> <li>Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms and as clinically indicated.</li> <li>BLNREP is only available through the BLNREP Risk Evaluation and Mitigation Strategy (REMS).</li> </ol> <p><b>BLNREP REMS:</b> <a href="http://www.BLNREPREMS.com">www.BLNREPREMS.com</a> or 1-855-690-9572.</p> <p>BLNREP has also been associated with:</p> <ol style="list-style-type: none"> <li>Thrombocytopenia</li> <li>Embryo-fetal Toxicity</li> </ol> <p>Patients should be monitored for any of these reactions. BLNREP dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.</p>																

	<p>BLENREP can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating BLENREP treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with BLENREP and for <b>four months</b> after the last dose.</p> <p>Advise males with female partners of reproductive potential to use effective contraception during treatment and for <b>six months</b> after the last dose.</p>	
<p><b>Approval Criteria</b></p> <p><b>Multiple Myeloma</b></p>	<ul style="list-style-type: none"> <li>a. Physician administered IV infusion; in-office or HOPD               <ul style="list-style-type: none"> <li>i. Cannot be self-administered</li> </ul> </li> <li>b. Multiple Myeloma (<b>must meet all</b>):               <ul style="list-style-type: none"> <li>i. Diagnosis of relapsed or refractory Multiple Myeloma</li> <li>ii. Received at least two prior lines of therapy, including a proteasome inhibitor AND an immunomodulatory agent (See Appendix)</li> <li>iii. Prescribed by or in consultation with an oncologist</li> <li>iv. Patient age <math>\geq</math> 18 years</li> <li>v. First eight cycles used in conjunction with bortezomib + dexamethasone</li> <li>vi. Request meets one of the following:                   <ul style="list-style-type: none"> <li>1. Dose does not exceed 2.5 mg/kg (actual BW) every three weeks (21-day cycle)</li> <li>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)</li> </ul> </li> </ul> </li> </ul>	
<b>Age Restriction</b>	Adults $\geq$ 18 years old	
<b>Coverage Duration</b>	<p><b>Initial:</b> six months. <b>Reauthorization:</b> 12 months.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p>	
<b>Other Criteria (LCD, NCD, etc.)</b>	Must follow LCD <a href="#">L37205</a> – Chemotherapy Drugs and their Adjuncts	
<b>Misc Info, Appendix Etc.</b>	<b>Examples of proteasome inhibitors for treatment of Multiple Myeloma</b>	<b>Examples of immunomodulatory agents for treatment of Multiple Myeloma</b>
	<ul style="list-style-type: none"> <li>a. Bortezomib</li> <li>b. Kyprolis</li> <li>c. Ninlaro</li> </ul>	<ul style="list-style-type: none"> <li>a. Pomalidomide</li> <li>b. Revlimid</li> <li>c. Thalomid</li> </ul>

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/6/26	1/6/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26