New Medical Drug-Related Prior Authorization Requirements for Zolgensma

Effective April 8, 2019, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) will expand utilization management requirements for Medicare Advantage and commercial lines of business to require prior authorization (PA) for the new medical drug Zolgensma, when approved by the Food and Drug Administration (FDA).

As stewards of healthcare expenditures for our subscribers, we are charged with ensuring they receive the highest quality, evidence-based care. This is accomplished through expanded development of medical policies and through management of these policies to include the PA process. The primary purpose of the PA process is to ensure that evidence-based care is provided to our subscribers, driving quality, safety, and affordability.

PA Requirements: starting April 8, 2019, a medical drug PA will be required for the following drugs as they are approved by FDA and become available for use:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Policy</th>
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</thead>
<tbody>
<tr>
<td>Onasemnogene abeparvovec-xxxx (ZOLGENSMA®)</td>
<td>Commercial: II-173</td>
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<td></td>
<td>Medicare: L33394</td>
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</tbody>
</table>

Products Impacted

This PA program applies to subscribers that have coverage through Medicare Advantage and commercial health plans (excluding Federal Employee Program (FEP) which has separate PA requirements).

Submitting a PA Request when Applicable

- Before submitting a PA request, Providers are asked to check applicable Blue Cross policy and attach all required clinical documentation with the request. PA requests will be reviewed when patient-specific, relevant medical documentation has been provided supporting the medical necessity of the service. Failure to submit required information may result in review delays (if outreach is needed to obtain missing clinical information) or a denial of the request due to insufficient information. If a provider does not obtain the required PA before rendering services, Blue Cross will deny claims as provider liability for lack of prior authorization.
- PA approval will be based on the Blue Cross policy criteria. To review Blue Cross criteria:
  - Go to providers.bluecrossmn.com
  - Under Tools & Resources, select “Medical Policy”, and read/accept the Blue Cross Medical Policy Statement
  - Select the “+” (plus) sign next to Medical and Behavioral Health Policies, then select “Blue Cross Blue Shield of Minnesota Medical Policies” to access policy criteria

Continued
• Prior Authorization Lists are updated to reflect additional PA requirements on the effective date of the management change and includes applicable codes. To access Prior Authorization Lists for all lines of business:
  o Go to providers.bluecrossmn.com
  o Under Tools & Resources, select “Medical Policy”, and read/accept the Blue Cross Medical Policy Statement
  o Select the “+” (plus) sign next to “Utilization Management” to access the Prior Authorization Lists.
• If a provider does not obtain the required PA before rendering services, Blue Cross will deny claims as provider liability for lack of prior authorization. The requirement applies to subscribers starting therapy and to those already being treated with a therapy noted above.
• Providers may submit PA requests for any treatment in the above table after the FDA approves the drug.

Providers can Submit an Electronic Prior Authorization (ePA) Request
• Online via our free Availity provider portal – for Blue Cross to review.
• For Medical Drugs, PA’s can also be submitted using a NCPDP standard XML file feed to Blue Cross through CenterX, via an integrated Electronic Medical Record (EMR) system. To learn how to do this, providers should contact their EMR vendor for assistance.
• Out of state, non-contracted providers can submit a PA request to Blue Cross by either using the electronic processes above, the Minnesota Uniform Form for PA Request and Formulary Exceptions fax form located under the Forms section on the Blue Cross website, or their own PA form (secure fax: 651.662.2810). Note: An approved PA does not guarantee coverage under a subscriber’s benefit plan. Subscriber benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies.

Reminder Regarding Medical Policy Updates & Changes
Medical Policy changes are communicated in the Upcoming Medical Policy Notifications section of the Blue Cross Medical and Behavioral Health Policy website. The Upcoming Policies section lists new, revised, or inactivated policies approved by the Blue Cross Medical and Behavioral Health Policy Committee and are effective at minimum 45 days from the date they were posted. To access the website:
• Go to providers.bluecrossmn.com
• Under Tools & Resources, select “Medical Policy”, and read/accept the Blue Cross Medical Policy Statement
• Select the “+” (plus) sign next to “Medical and Behavioral Health Policies” to see the Upcoming Medical Policy Notifications section

Questions?
If you have questions, please contact provider services at (651) 662-5200 or 1-800-262-0820.