ForwardHealth
Wisconsin serving you

Update
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Affected Programs: BadgerCare Plus, Medicaid, SeniorCare
To: Federally Qualified Health Centers, Hospital Providers, Nurse Practitioners, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Rural Health Clinics, HMOs and Other Managed Care Programs

Prior Authorization Required for Spinraza™

Effective for dates of service on and after April 1, 2017, Spinraza™, a drug used to treat spinal muscular atrophy, requires clinical prior authorization.

Effective for dates of service on and after April 1, 2017, Spinraza™, a drug used to treat spinal muscular atrophy (SMA), requires clinical prior authorization (PA). Spinraza™ will be reimbursed separately from physician and clinical services associated with the administration of Spinraza™. Providers should submit claims for Spinraza™ to ForwardHealth using a noncompound drug claim. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that Spinraza™ is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for Spinraza™ that has been administered to a member. If Spinraza™ has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Spinraza™ that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.

Clinical Criteria for Spinraza™

Clinical criteria that must be documented and submitted in medical records (e.g., chart notes, laboratory values) for approval of an initial PA request for Spinraza™ are **all** of the following:

- Spinraza™ must be prescribed by a neurologist, pulmonologist, or other physician with expertise in treating SMA.
- The member has SMA type 1, 2, or 3, which has been confirmed by genetic testing (5q SMN1: homozygous mutation, homozygous gene deletion, or compound heterozygote).
- The member has **at least two** copies of the SMN2 gene.
- The member initiated medical treatment with Spinraza™ for SMA before 21 years of age.
- The prescriber submits exam values of **at least one** of the following exams (based on member age and motor ability) to establish baseline motor ability:
  - ✓ Hammersmith Infant Neurological Examination (HINE) (infant to early childhood)
  - ✓ Hammersmith Functional Motor Scale — Expanded
  - ✓ Upper Limb Module test (non-ambulatory members)
  - ✓ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders
  - ✓ Six-minute walk test (ambulatory members)
- The prescriber indicates the member's pulmonary status, including any requirement for ventilator support.

ForwardHealth will deny PA requests for Spinraza™ if **any** of the following circumstances are present:

- The member is dependent on **either** of the following:
  - ✓ Invasive ventilation or tracheostomy.
  - ✓ Non-invasive ventilation beyond use for naps and nighttime sleep.
- The member is currently involved in a clinical trial for Spinraza™.
- The member is diagnosed with a non-SMN1 variant of SMA.
- The member is pre-symptomatic. (*Note:* ForwardHealth will consider PA requests for a member who is an infant and has not yet developed symptoms but has undergone genetic studies indicating a high likelihood of developing type 1, 2, or 3 SMA disease [i.e., less than three copies of the SMN2 gene].)

Initial PA requests for Spinraza™ to treat SMA may be approved for up to a maximum of 210 days to allow for up to five doses of Spinraza™.

Renewal Prior Authorization Requests

In addition to meeting the clinical criteria for initial PA request approval, renewal PA requests for Spinraza™ require the submission of medical records (e.g., chart notes, laboratory values) with the most recent results (less than one month prior to the submission of the renewal PA request) documenting a positive clinical response to Spinraza™ therapy **from pretreatment baseline status** as demonstrated by **at least one** of the following exams:

- Hammersmith Infant Neurological Examination that demonstrates **two** of the following:
  - ✓ Improvement or maintenance of previous improvement of at least a two-point (or maximal score) increase in ability to kick
    or
  - ✓ Improvement or maintenance of previous improvement of at least a one-point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling), excluding voluntary grasp
    and
  - ✓ Improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (i.e., net positive improvement)
    or
  - ✓ Achievement and maintenance of any new motor milestone(s) from pretreatment baseline when the member would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)
- Hammersmith Functional Motor Scale — Expanded that demonstrates **one** of the following:
  - ✓ Improvement or maintenance of previous improvement of at least a three-point increase in score from pretreatment baseline.
  - ✓ Achievement and maintenance of any new motor milestone(s) from pretreatment baseline when the member would otherwise be unexpected to do so.
- Upper Limb Module test that demonstrates **one** of the following:
  - ✓ Improvement or maintenance of previous improvement of at least a two-point increase in score from pretreatment baseline.
  - ✓ Achievement and maintenance any new motor milestone(s) from pretreatment baseline when the member would otherwise be unexpected to do so.
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders that demonstrates **one** of the following:
  - ✓ Improvement or maintenance of previous improvement of at least a four-point increase in score from pretreatment baseline.
  - ✓ Achievement and maintenance of any new motor milestone(s) from pretreatment baseline when the member would otherwise be unexpected to do so.

Renewal PA requests for Spinraza™ used to treat SMA may be approved for up to a maximum of 365 days.

Submitting Prior Authorization Requests for Spinraza™

Prior authorization requests for Spinraza™ must be submitted using the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016).

As a reminder, when completing the PA/DGA form, prescribers should provide the diagnosis code and description, complete Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook), and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a Prior Authorization Request Form (PA/RF), F-11018 (05/13), before submitting the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

Prior authorization requests for Spinraza™ may be submitted on the Portal, by fax, or by mail (but **not** using the Specialized Transmission Approval Technology-Prior Authorization system).

Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy for members enrolled in Medicaid and BadgerCare Plus who receive pharmacy services on a fee-for-service basis only. Pharmacy services for Medicaid members enrolled in the Program of All-Inclusive Care for the Elderly (PACE) and the Family Care Partnership are provided by the member's managed care organization.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Medicaid Services, the Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, DHS.

For questions, call Provider Services at 800-947-9627 or visit our website at *www.forwardhealth.wi.gov/*.

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