ForwardHealth
Wisconsin serving you

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

ForwardHealth Interim Coverage of Select Drugs, Including High Cost Drugs, Orphan Drugs, and Drugs Approved Under an FDA Accelerated Approval Pathway

ForwardHealth has created the new Select High Cost, Orphan, and Accelerated Approval Drugs data table to serve as a provider reference for interim billing and coverage information of select high cost drugs, orphan drugs, and drugs approved under a Food and Drug Administration (FDA) accelerated approval pathway. Effective for dates of service (DOS) on and after December 3, 2018, ForwardHealth has also established prior authorization (PA) policy and clinical criteria for approval of PA requests for the following drugs on the Select High Cost, Orphan, and Accelerated Approval Drugs data table:

- Endari
- Luxturna
- Palynziq
- Crysvita
- Exondys 51
- Mepsevii

Select High Cost, Orphan, and Accelerated Approval Drugs Data Table

For DOS on and after December 3, 2018, providers should refer to the new Select High Cost, Orphan, and Accelerated Approval Drugs data table on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal for a list of select high cost, orphan, and accelerated approval drugs and interim billing and coverage information for these drugs. The table will also identify which drugs have specific PA or policy requirements. The Select High Cost, Orphan, and Accelerated Approval Drugs data table will be updated regularly; it is the provider's responsibility to remain up-to-date with the information included on the data table.

Inquiries Regarding Select High Cost, Orphan, and Accelerated Approval Drugs

For specific questions about the billing or coverage of high cost, orphan, and accelerated approval drugs listed in the Select High Cost, Orphan, and Accelerated Approval Drugs data table, providers may contact Provider Services at 800-947-9627 or email *DHSOrphanDrugs@dhs.wisconsin.gov*.

Claims Submission for Select High Cost, Orphan, and Accelerated Approval Drugs

For the interim, select high cost, orphan, and accelerated approval drugs will be covered and reimbursed under the pharmacy benefit. When a noncompound drug is covered under the pharmacy benefit, providers may submit claims for

the cost of the drug to ForwardHealth through one of the following methods:

- Real-time point-of-sale system using the National Council for Prescription Drug Programs Telecommunication Standard
- ForwardHealth Portal
- Provider Electronic Solutions software
- Noncompound Drug Claim form, F-13072 (04/2017)

Related physician and clinical services associated with the administration of the drug will be reimbursed separately based on existing coverage and reimbursement policy.

Pharmacy Direct Billing for Select High Cost, Orphan, and Accelerated Approval Drugs

To clarify, if a provider or facility obtains a drug that is specifically addressed in the Select High Cost, Orphan, and Accelerated Approval Drugs data table from a pharmacy provider, then the administering provider or facility may not bill for the cost of that drug because the pharmacy provider will bill for the cost of the drug.

It is the responsibility of the pharmacy provider to use appropriate management and packaging practices to ensure drug stability and integrity are maintained during drug shipment and delivery. Once the drug is in possession of the administering provider or facility, it is the responsibility of the administering provider or facility to use appropriate management and storage practices to ensure drug stability and integrity are maintained. If a drug is damaged prior to administration or is delivered but not administered to a member, ForwardHealth will not reimburse for the cost of the drug; it is the responsibility of the administering provider or facility to alert the pharmacy provider and the responsibility of the pharmacy provider to reverse its claim to ForwardHealth and work with the pharmaceutical company or administering provider or facility regarding payment for the damaged or wasted drug.

For the interim, select high cost, orphan, and accelerated approval drugs will be covered under the pharmacy benefit, but it is the responsibility of the healthcare provider to determine the medically appropriate setting for administration. Providers are required to comply with all relevant safety protocols when administering these drugs to ForwardHealth members.

For specific questions about institutional billing or coverage of high cost, orphan, and accelerated approval drugs listed in the Select High Cost, Orphan, and Accelerated Approval Drugs data table, providers may contact Provider Services at 800-947-9627 or email *DHSOrphanDrugs@dhs.wisconsin.gov*.

Note: Select high cost, orphan, and accelerated approval drugs covered under the pharmacy benefit will not be covered as provider-administered drugs. When a high cost, orphan, or accelerated approval drug is covered under the pharmacy benefit, it will be reimbursed fee-for-service and managed care organizations (MCOs) will not be responsible for the cost of the drug, but MCOs are still responsible for the physician and clinical services associated with the high cost, orphan, or accelerated approval drug.

Coordination of Benefits

Claims will be subject to ForwardHealth's coordination of benefits (COB) policy. Providers should reference the ForwardHealth Online Handbook for COB information.

Clinical Criteria for Select High Cost, Orphan, and Accelerated Approval Drugs with Drug-Specific Criteria

ForwardHealth has established clinical criteria for approval of PA requests for the following drugs on the Select High Cost, Orphan, and Accelerated Approval Drugs data table:

- Endari
- Luxturna
- Palynziq

Endari

Endari requires clinical PA. For PA requests for Endari, the prescriber is required to complete, sign, and date the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016), using Section VI (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the form. The prescriber is required to

send the completed PA/DGA form to the pharmacy where the prescription will be filled. The pharmacy provider is required to complete a Prior Authorization Request Form (PA/RF), F-11018 (05/13), and submit it, along with the PA/DGA form received from the prescriber, to ForwardHealth using the PA submission option most appropriate for the drug.

PA requests for Endari may be submitted on the Portal, by fax, or by mail (but **not** using the Specialized Transmission Approval Technology-Prior Authorization [STAT-PA] system).

Clinical Criteria for Endari

Clinical criteria that must be documented for approval of a PA request for Endari are **all** of the following:

- The member has been diagnosed with sickle cell disease (SCD).
- The member is 5 years of age or older.
- The member's current weight is provided.
- The dose requested is consistent with the FDA-recommended daily dosage (5 g to 15 g twice daily based on body weight).
- The prescription is written by a hematologist or a provider who specializes in SCD.
- The prescriber has documented the frequency of sickle cell crisis experienced by the member in the past 12 months, with evidence of at least one sickle cell crisis in the past year. Documentation should include the type of crisis, the approximate dates, and what interventions took place. Sickle cell crisis is defined as **one or more** of the following:
  - ✓ The member had an emergency room visit/medical facility visit for sickle cell disease-related pain treated with parenteral opioid or parenteral ketorolac.
  - ✓ The member had acute chest syndrome.
  - ✓ The member had priapism.
  - ✓ The member had splenic sequestration.
  - ✓ The member had a venous thromboembolism, myocardial infarction, stroke, or transient ischemic attack thought to be related to sickle cell disease.
  - ✓ The member had dactylitis or bone infarction.
- **At least one** of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with hydroxyurea.
  - ✓ There is a clinically significant drug interaction between another drug(s) the member is taking and hydroxyurea.
  - ✓ The member has a medical condition(s) that prevents the use of hydroxyurea.
- A copy of the member's medical records must be submitted and should document the following:
  - ✓ The medical record contains sufficient documentation to satisfy the clinical coverage criteria above.
  - ✓ The medical record contains details regarding previous medication use.
  - ✓ The medical record describes the member's current treatment plan.

The following will **not** be considered as criteria to support the need for Endari:

- Nonadherence to previous therapies for SCD
- Member or prescriber preference

If clinical criteria for Endari are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for Endari may be approved for up to 365 days.

Renewal PA requests for members who have SCD must meet the clinical criteria for initial PA requests for Endari and have documentation to support that the member has experienced a reduction in the number of sickle cell crises since starting Endari treatment. All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of the current medical records must be included with the PA request.

Luxturna

Luxturna requires clinical PA. For PA requests for Luxturna, the prescriber is required to complete, sign, and date the PA/DGA form, using Section VI (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the form. The

prescriber is required to send the completed PA/DGA form to the pharmacy where the prescription will be filled. The pharmacy provider is required to complete a PA/RF and submit it, along with the PA/DGA form received from the prescriber, to ForwardHealth using the PA submission option most appropriate for the drug.

PA requests for Luxturna may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

Clinical Criteria for Luxturna

Clinical criteria that must be documented for approval of a PA request for Luxturna are **all** of the following:

- The member has a confirmed diagnosis of an inherited retinal dystrophy due to biallelic RPE65 mutations.
- The member has sufficient viable retinal cells (defined as an area of retinal thickness >100 microns within the posterior pole) as measured by optical coherence tomography.
- The member has remaining light perception in the eye(s) that will receive treatment.
- Luxturna is prescribed and administered by an ophthalmologist or retinal surgeon with experience providing subretinal injections.

If clinical criteria for Luxturna are met, PA requests may be approved on a unilateral basis for up to four weeks (one lifetime dose per eye). For consideration of continued therapy on the second eye, **all** of the following must apply:

- All clinical criteria for initial PA request approval must be met.
- Administration is planned within a close interval to the treatment of the first eye, but at least six days apart.
- The PA request is not for a repeat treatment of a previously treated eye.

Palynziq

Palynziq requires clinical PA. For PA requests for Palynziq, the prescriber is required to complete, sign, and date the PA/DGA form, using Section VI (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the form. The prescriber is required to send the completed PA/DGA form to the pharmacy where the prescription will be filled. The pharmacy provider is required to complete a PA/RF and submit it, along with the PA/DGA form received from the prescriber, to ForwardHealth using the PA submission option most appropriate for the drug.

PA requests for Palynziq may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

Clinical Criteria for Palynziq

Clinical criteria that must be documented for approval of a PA request for Palynziq for the treatment of adult members 18 years of age or older with a documented diagnosis of phenylketonuria are **all** of the following:

- The member has blood phenylalanine (Phe) levels greater than 600 micromole/L on existing management (e.g., restriction of dietary phenylalanine and protein intake).
- **At least one** of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with sapropterin (Kuvan).
  - ✓ There is a clinically significant drug interaction between another drug(s) the member is taking and sapropterin (Kuvan).
  - ✓ The member has a medical condition(s) that prevents the use of sapropterin (Kuvan).
- Blood Phe levels will be obtained every four weeks until a maintenance dose is established. The drug dose should be titrated to the lowest effective dose. Once a maintenance dose is established, Phe levels will be monitored every six months.
- A copy of the member's medical records must be submitted and should document the following:
  - ✓ The medical record contains sufficient documentation to satisfy the clinical coverage criteria above.
  - ✓ The medical record contains details regarding previous medication use.
  - ✓ The medical record describes the member's current treatment plan.

If clinical criteria for Palynziq are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for Palynziq may be approved for up to 365 days.

In addition to meeting the clinical criteria for initial PA request approval, renewal PA requests for Palynziq require the submission of medical records (e.g., chart notes, laboratory values) with the most recent results to demonstrate at least one of the following:

- The member has achieved at least a 20 percent reduction in blood Phe level from pretreatment baseline.
- The member has achieved a blood Phe level less than or equal to 600 micromole/L.

Select High Cost, Orphan, or Accelerated Approval Drugs

PA Requirements for Select High Cost, Orphan, or Accelerated Approval Drugs

Select high cost, orphan, or accelerated approval drugs may require PA, but in some cases, ForwardHealth will not establish drug-specific clinical criteria. For PA requests for select high cost, orphan, or accelerated approval drugs without drug-specific clinical criteria, the prescriber is required to complete, sign, and date the PA/DGA form, using Section VII (Clinical Information for Other Drug Requests) of the form. The prescriber is required to send the completed PA/DGA form to the pharmacy where the prescription will be filled. The pharmacy provider is required to complete a PA/RF and submit it, along with the PA/DGA form received from the prescriber, to ForwardHealth using the PA submission option most appropriate for the drug.

If a high cost, orphan, or accelerated approval drug requires PA, but drug-specific clinical criteria are not established, PA requests for these drugs require the submission of medical records (e.g., chart notes, laboratory values) to support that the drug being prescribed is for an FDA-approved indication and is medically necessary as defined by Wis. Admin. Code § DHS 101.03(96m). The drug must be prescribed in a dose and manner consistent with FDA-approved product labeling. These PA requests will be reviewed on a case-by-case basis for medical necessity.

PA requests for these drugs may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

Clinical Criteria for Select High Cost, Orphan, or Accelerated Approval Drugs

The following orphan drugs require PA to support that the drugs will be used for an FDA-approved indication; PA requests for these drugs will be reviewed on a case-by-case basis for medical necessity:

- Crysvita
- Exondys 51
- Mepsevii

As new high cost, orphan, and accelerated approval drugs enter the market, ForwardHealth will use the Select High Cost, Orphan, and Accelerated Approval Drugs data table to identify whether or not these drugs require PA. For drugs that require PA, the table will indicate whether or not the drugs have drug-specific PA clinical criteria.

Reminder of Out-of-State Policy

As a reminder, out-of-state providers are required to submit PA requests for non-emergency services. For more information about submitting PA requests for out-of-state pharmacy services, providers may refer to the Prior Authorization/Drug Attachment topic (topic #15937) in the Forms and Attachments chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Information Regarding MCOs

This *ForwardHealth 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 MCO.

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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