February 2022 DUR Board Meeting Minutes

Date: February 23, 2022

Members Present: King, Anglim, Blake, Brown, Caldwell, Jost, McGrane, Nauts, Putsch, Stone

Members Absent: Blank, Maxwell

Others Present: Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Artis, Bahny, Barnhill, Doppler, Erickson, Miranda, Woodmansey (MPQH); representatives of the pharmaceutical industry.

Introductions: Tony King opened the meeting, introduced Jennifer Miranda, the new clinical pharmacist for Mountain-Pacific Quality Health (MPQH) Pharmacy Case Management, and outlined the new public comment procedure. He then provided an opportunity for public comment for those who signed up prior to the meeting.

Public Comment: Kathryn Lanza, NS Pharma, Viltepso® representative

Meeting Minute Review: The meeting minutes from the November 9, 2021 DUR Board Meeting were approved as written.

Department Update: No Department update.

Board Discussion

1. **Exon Skipping Therapy Continued Discussion**

A. Exondys 51™ (eteplirsen)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.
    - The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to Exon 51 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
    - Genetic mutation test results must be submitted with request.
- Must be prescribed by, or in consult with a neurology specialist.
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Exondys 51®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Exondys 51®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- If ambulatory, baseline functional level assessment required by one of the following:
    - Six-minute walk test (6MWT)
    - NorthStar Ambulatory Assessment
- If non-ambulatory, baseline functional level assessment required by one of the following:
    - Revised Upper Limb Module (RULM)
    - Performance Upper Limb (PUL)
- Exondys 51® is not used concomitantly with other exon skipping therapies for DMD.
- Initial coverage duration is for 6 months.
- Quantity Limitations are max of 30mg/kg IV once weekly.

Renewal Coverage Criteria (member must meet *all of the following criteria*):

- Member has been adherent to Exondys 51®.
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Functional level assessment must be completed every 6-months, using the same rating scale utilized at baseline, and submitted with renewal request.
- Member is receiving a benefit from Exondys 51® therapy, as demonstrated by one of the following:
    - Stabilization or improvement compared to baseline functional level assessment utilizing the same rating scale submitted in initial approval.
    - Provider attests that member requires continued use of medication, despite not meeting improved baseline functional level assessment criteria and the benefits of continued use of medication outweigh the risks.
- Annual specialist consult provided if prescriber not a specialist.
- Renewal coverage duration is for 6 months.
- Quantity Limitations are max of 30mg/kg IV once weekly.

B. Vyondys 53™ (golodirsen)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
    - The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to Exon 53 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
    - Genetic mutation test results must be submitted with request.
- Must be prescribed by, or in consult with a neurology specialist.
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Vyondys 53®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Vyondys 53®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- If ambulatory, baseline functional level assessment required by one of the following:
    - Six-minute walk test (6MWT)
    - NorthStar Ambulatory Assessment
- If non-ambulatory, baseline functional level assessment required by one of the following:
    - Revised Upper Limb Module (RULM)
    - Performance Upper Limb (PUL)
- Vyondys 53® is not used concomitantly with other exon skipping therapies for DMD.
- Initial coverage duration is 6 months.
- Quantity limitations are max of 30mg/kg IV once weekly.

Renewal Coverage Criteria (member must meet *all of the following criteria*):

- Member has been adherent to Vyondys 53®.
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Functional level assessment must be completed every 6-months, using the same rating scale utilized at baseline, and submitted with renewal request.

- Member is receiving a benefit from Vyondys 53® therapy, as demonstrated by one of the following:
    - Stabilization or improvement compared to baseline functional level assessment utilizing the same rating scale submitted in initial approval.
    - Provider attests that member requires continued use of medication, despite not meeting improved baseline functional level assessment criteria and the benefits of continued use of medication outweigh the risks.
- Annual specialist consult provided if prescriber not a specialist.
- Renewal coverage duration is 6 months.
- Quantity limitations are max of 30mg/kg IV once weekly.

C. Viltepso™ (viltolarsen)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
    - The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to Exon 53 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
    - Genetic mutation test results must be submitted with request.
- Must be prescribed by, or in consult with a neurology specialist.
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Viltepso®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Viltepso®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- If ambulatory, baseline functional level assessment required by one of the following:
    - Six-minute walk test (6MWT)
    - NorthStar Ambulatory Assessment
- If non-ambulatory, baseline functional level assessment required by one of the following:
    - Revised Upper Limb Module (RULM)
    - Performance Upper Limb (PUL)
- Viltepso® is not used concomitantly with other exon skipping therapies for DMD.
- Initial coverage duration is 6 months.
- Quantity limitations are max of 80mg/kg IV once weekly.

Renewal Coverage Criteria (member must meet *all of the following criteria*):

- Member has been adherent to Viltepso®.
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Functional level assessment must be completed every 6-months, using the same rating scale utilized at baseline, and submitted with renewal request.
- Member is receiving a benefit from Viltepso® therapy, as demonstrated by one of the following:
    - Stabilization or improvement compared to baseline functional level assessment utilizing the same rating scale submitted in initial approval.
    - Provider attests that member requires continued use of medication, despite not meeting improved baseline functional level assessment criteria and the benefits of continued use of medication outweigh the risks.
- Annual specialist consult provided if prescriber not a specialist.
- Renewal coverage duration is 6 months.

- Quantity limitations are max of 80mg/kg IV once weekly.

D. Amondys 45™ (casimersen)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
    - The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to Exon 45 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
    - Genetic mutation test results must be submitted with request.
- Must be prescribed by, or in consult with a neurology specialist.
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Amondys 45®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Amondys 45®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- If ambulatory, baseline functional level assessment required by one of the following:
    - Six-minute walk test (6MWT)
    - NorthStar Ambulatory Assessment
- If non-ambulatory, baseline functional level assessment required by one of the following:
    - Revised Upper Limb Module (RULM)
    - Performance Upper Limb (PUL)
- Amondys 45® is not used concomitantly with other exon skipping therapies for DMD.
- Initial coverage duration is 6 months.
- Quantity limitations are max of 30mg/kg IV once weekly.

Renewal Coverage Criteria (member must meet *all of the following criteria*):

- Member has been adherent to Amondys 45®.
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Functional level assessment must be completed every 6-months, using the same rating scale utilized at baseline, and submitted with renewal request.
- Member is receiving a benefit from Amondys 45® therapy, as demonstrated by one of the following:
    - Stabilization or improvement compared to baseline functional level assessment utilizing the same rating scale submitted in initial approval.
    - Provider attests that member requires continued use of medication, despite not meeting improved baseline functional level assessment criteria and the benefits of continued use of medication outweigh the risks.
- Annual specialist consult provided if prescriber not a specialist.
- Renewal coverage duration is 6 months.
- Quantity limitations are max of 30mg/kg IV once weekly.

2. Specialist Definition Discussion

Discussion is ongoing and has been tabled for a future meeting. MPQH staff will review current drug criteria with specialist requirements for advisement at future meetings.

Closed Session: No cases to present.

The meeting adjourned at 2:55pm.