

| Field Name                            | Field Description  |
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| Prior Authorization Group Description | <b>Antisense Oligonucleotides for Duchenne Muscular Dystrophy</b>  |
| Drugs                                 | Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Amondys 45 (casimersen)  |
| Covered Uses                          | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.  |
| Exclusion Criteria                    | Concomitant use with another antisense oligonucleotide   |
| Required Medical Information          | See “Other Criteria”   |
| Age Restrictions                      | Age ≤ 20 years   |
| Prescriber Restrictions               | Prescribed by neurologist or provider who specializes in the treatment of DMD  |
| Coverage Duration                     | If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.   |
| Other Criteria                        | <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following: <ul style="list-style-type: none"> <li>Exon 51 skipping for Exondys 51</li> <li>Exon 53 skipping for Vyondys 53 or Viltepso</li> <li>Exon 45 skipping for Amondys 45</li> </ul> </li> <li>Member is ambulatory</li> <li>Baseline dystrophin levels AND results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)]</li> <li>Member has stable pulmonary and cardiac function</li> <li>Member is on a stable dose of corticosteroids</li> <li>Attestation of renal function monitoring is provided with request</li> <li>The request is for an FDA approved dose</li> </ul> <p><b><u>Reauthorization</u></b></p> <ul style="list-style-type: none"> <li>Documentation is provided that the member had an increase in dystrophin levels from baseline</li> </ul> |

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| <p>Revision/Review Date<br/>12/2023</p> | <ul style="list-style-type: none"> <li>• Documentation is provided that the member had the expected clinical response (e.g. provider statement that the therapy has reduced the rate of further decline in function as demonstrated by 6MWT, TTSTAND, TTRW, NSAA, or TTCLIMB)</li> <li>• Member is ambulatory</li> <li>• Attestation of renal function monitoring is provided with request</li> <li>• The request is for an FDA approved dose</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p> |
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