The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Orphan Drug Policy

Drug(s): VELCADE (bortezomib), ZOLINZA (vorinostat), ADAGEN (pegademase bovine), ALDURAZYME (laronidase), ELAPRASE (idursulfase), MYOZYME (alglucosidase alfa), NAGLAZYME (galsulfase), Kuvan (sapropterin).

Covered Uses: Orphan drugs or FDA approved drugs designated with an orphan drug indication may be covered on a case-by-case basis, with prior authorization, for the FDA approved indications only. Only drugs FDA approved for marketing as Orphan Drugs or Biologics will be considered for coverage under this policy. All FDA-approved indications not otherwise excluded from Part D.

Required Medical Information: Medical history and relevant chart notes, lab results, radiologic reports, biopsy report, etc.

Age Restrictions: Per package label.

Prescriber Restrictions: A plan-affiliated specialist, familiar with the treatment of the rare disease or condition, must prescribe the drug.

Other Criteria: Physician and member must comply with all approved and/or limited distribution channels for the agent including specialty pharmacy vendors where applicable.

Exclusion Criteria: The use of orphan drugs and biologics will not be considered medically necessary for the following situations:

- Off-label use,
- member has not failed all other standard therapies for the disease,
- FDA warnings and contraindications for the use of the drug have not been addressed by the prescriber.

Coverage Duration: Initial approval for 3 months unless not medically indicated. Coverage up to 6 months with an extension.