Health Alliance™ Pharmacy Drug Policy Checklist

POLICY NAME	Medications Excluded due to Lack of Clinical	POLICY #	3138P

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ Antisense Oligonucleotides and other therapies used for Duchenne muscular dystrophy (Amondys 45, Exondys 51, Vyondys 53, Viltepso)
  - Amondys 45, Exondys 51, Vyondys 53, and Viltepso were approved under accelerated approval based on an increase in dystrophin production in skeletal muscle. Clinical benefit has not yet been shown.
- ☐ Anti-amyloid immune globulin monoclonal antibody used for Alzheimer's disease (Aduhelm)
  - Aduhelm was approved under accelerated approval based on a reduction of amyloid beta plaque. Clinical benefit has not yet been shown.
- ☐ Immunotherapy used for cerebral adrenoleukodystrophy (Skysona)
  - Syksona was approved under accelerated approval based on the potential ability to increase production of adrenoleukodystrophy proteins through gene therapy and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. Clinical benefit has not yet been shown.
- ☐ Immunotherapy used for Transfusion-dependent beta-thaassemia (Zynteglo)
  - Zynteglo was approved under accelerated approval based on the potential ability to increase red blood cell production through gene therapy and continued approval is contingent upon verification and description of clinical benefit in confirmatory trials. Clinical benefit has not yet been shown based on currently available studies and literature.
- ☐ Antisense oligonucleotide used for amyotrophic lateral sclerosis (Qalsody)
  - Qalsody was approved under accelerated approval based on a reduction in plasma neurofilament light. Qalsody did not demonstrate clinical benefit over placebo based on the Statement of the Policy References Revised Amyotrophic Lateral Sclerosis Functional Rating Scale scores. Continued approval is contingent upon verification and description of clinical benefit in confirmatory trials. Clinical benefit has not yet been shown.
- ☐ Angiotensin II Receptor Blocker (ARB)/Endothelin Receptor Antagonist (ERA) for IgA nephropathy (Filspari)
  - Filspari was approved under accelerated approval based on a reduction in proteinuria. Filspari did not demonstrate clinical benefit over placebo in slowing decline of kidney function. Continued approval is contingent upon verification and description of clinical benefit in confirmatory trials. Clinical benefit has not yet been shown.

☐ Thyroid receptor beta agonists used for noncirrhotic nonalcoholic steatohepatitis (Rezdiffra)

- Rezdiffra was approved under accelerated approval based on a potential improvement in steatohepatitis or fibrosis independently inferred from liver biopsy. Continued approval is contingent upon verification and description of clinical benefit in confirmatory trials. Clinical benefit has not yet been shown CPT Codes HCPCS Codes