

Policy Name:	Medications Excluded due to Lack of Clinical Benefit	Policy#:	3138P
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Purpose of the Policy

The purpose of this policy is to ensure medications with lack of clinical benefit are not covered under the pharmacy benefit. This list is coordinated and overseen by the Pharmacy and Therapeutics (P&T) Committee and is subject to change

Statement of the Policy

This policy lists the drugs that are excluded from coverage under the Health Alliance Medical Plans pharmacy benefit due to lack of clinical benefit. Package inserts for these medications mention continued approval for their indications may be contingent upon verification of a clinical benefit in a confirmatory trial.

Criteria

1. The following medications are not covered due to lack of clinical benefit:

- 1.1 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.
- 1.2 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.
- 1.3 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.
- 1.4 Immunotherapy used for Transfusion-dependent beta-thalassemia (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.
- 1.5 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

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.

- 1.6 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.
- 1.7 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	

References

- Aduhelm (aducanumab-avwa) [prescribing information]. Cambridge, MA: Biogen Inc; June 2021.
- Amondys 45 (casimersen) [prescribing information]. Cambridge, MA: Sarpeta Therapeutics, Inc; February 2021.
- Exondys 51 (eteplirsen) [prescribing information]. Cambridge, MA: Sarpeta Therapeutics, Inc; September 2016.
- Viltepso (viltolarsen) [prescribing information]. Paramus, MA: NS Pharma, Inc; August 2020.
- Vyondys 53 (golodirsen) [prescribing information]. Cambridge, MA: Sarpeta Therapeutics, Inc; December 2019.
- Skysona (elivaldogene autotemcel) [prescribing information]. Somerville, MA: Bluebird Bio Inc; September 2022.
- Zynteglo (betibeglogene autotemcel) [prescribing information]. Somerville, MA: Bluebird Bio Inc; August 2022.
- Qalsody (tofersen) [prescribing information]. Cambridge, MA: Biogen MA Inc; April 2023.
- Filspari (sparsentan) [prescribing information]. San Diego, CA: Travers Therapeutics, Inc; February 2023.
- Rezdiffra (resmetirom) [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc; March 2024.

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DISCLAIMER

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