West Virginia RDUR

2025 Quarter 4 Newsletter

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FDA APPROVAL SPOTLIGHT

Hereditary Angioedema

The Food and Drug Administration (FDA) has approved four treatments for the prevention and treatment of hereditary angioedema (HAE) in 2025.[1,2] HAE is a rare genetic disorder that causes recurrent, often unpredictable attacks of angioedema, typically involving the face, hands, feed, airways, and intestinal tract. The attacks may range in severity, but pose a significant risk of asphyxiation and can be life-threatening. Persons of all ages may be impacted by HAE, with both sexes impacted equally. Treatment of HAE is two-fold, with on-demand acute treatment and prophylaxis.

Orladeyo (berotralstat) pellets, Dawnzera (donidalorsen), and Andembry (garadacimab) were approved for the prophylaxis of HAE.[1,2] Of the three approvals, berotralstat pellets is the first and only oral product approved for HAE prophylaxis in patients aged 2 to 11.[2] Berotralstat pellets, approved December 12, 2025, is a new formulation of berotralstat. Berotralstat capsules were approved for HAE prophylaxis in patients aged 12 years and older in December 2020. The pellets, taken once daily, may be swallowed whole or mixed with soft food and are generally well tolerated. Currently, pricing is unknown on berotralstat pellets; however, the capsules have a yearly wholesale acquisition cost (WAC) of approximately $600k.

The most expensive prophylactic treatment currently available is the newly approved donidalorsen, at a yearly WAC of $747k for the recommended dosage interval. Approved on August 21, 2025, donidalorsen is a self-administered subcutaneous treatment for prophylaxis of HAE attacks in patients 12 years of age and older.[3] Donidalorsen offers a flexible dosing regimen with the ability to dose every 4 weeks up to every 8 weeks, dependent on patient ability and outcomes.[3]

The first of the 2025 HAE FDA approvals, garadacimab, approved on June 16, 2025, is a once monthly subcutaneous treatment indicated for HAE attack prophylaxis in patients aged 12 years and older.[4] Garadacimab has a yearly WAC of $685k at the recommended monthly dosing schedule.[4] Decision making for HAE prophylactic treatment will be dependent on patient adherence, access, administration, and outcomes.

Meanwhile, Ekterly (sebetralstat), approved on July 7, 2025, is the first and only oral on-demand treatment of acute attacks of HAE in patients 12 years of age and older.[5] Compared to placebo, sebetralstat significantly improved time to symptom relief, 1.79 hours versus 6.72 hours respectively.[5] At $16,720, the wholesale acquisition cost of sebetralstat is similar to other available on-demand treatments and potentially may dramatically improve patient access to on-demand treatment which

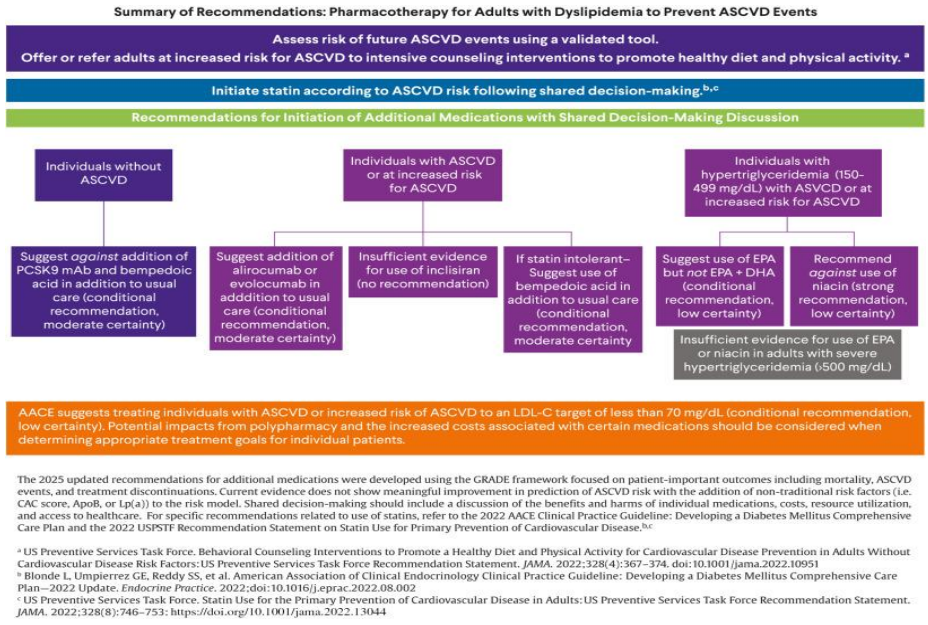
was previously limited to subcutaneous and intravenous products only. The increased access may lead to reduced provider and hospital associated costs of HAE.

References:

1. Center. Novel Drug Approvals for 2025. U.S. Food and Drug Administration. Published 2025. https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2025
2. BioCryst Pharmaceuticals, Inc.; Durham, NC. Orladeyo [package insert]. BioCrytst website. https://www.biocryst.com/wp-content/uploads/sites/13/2025/12/ORLADEYO_USPI.pdf
3. Ionis Pharmaceuticals, Inc.; Carsbad, CA. Dawnzera [package insert]. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219407s000lbl.pdf
4. CSL Behring LLC.; Kankakee, IL. Andembry [package insert]. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761367s000lbl.pdf
5. KalVista Pharmaceuticals, Inc.; Cambridge, MA. Ekterly [package insert]. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219301s000lbl.pdf

GUIDELINE UPDATES

American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults with Dyslipidemia



The 2025 American Association of Clinical Endocrinology (AACE) guideline on pharmacologic management of adults with dyslipidemia is an update to the 2017 guideline, to provide up-to-date, practical evidence-based recommendations for the management of dyslipidemia. The update includes 13 evidence-based recommendations for the pharmacologic management of adults with dyslipidemia focused on outcomes of atherosclerotic cardiovascular disease (ASCVD) risk reduction.

Summary of Recommendations
1. Utilize a validated tool or calculator to predict future risk of ASCVD events as a part of the shared decision-making process for treatment.
2. Add evolocumab or alirocumab to usual care for adults who are not at goal (LDL-C <70 mg/dL) and are at increased risk for ASCVD or adults with ASCVD and on maximally tolerated statins.
3. Do NOT add evolocumab or alirocumab in adults with dyslipidemia who do not have ASCVD or are not at increased risk for ASCVD.
4. No recommendation for or against the use of inclisiran in adults with dyslipidemia.
5. Add bempedoic acid to the usual care in adults with dyslipidemia who are statin *intolerant* and have ASCVD or are at increased risk for ASCVD.
6. Do NOT add bempedoic acid to the usual care for adults with dyslipidemia who do not have ASCVD and who may tolerate other lipid-lowering medications.
7. Add eicosapentaenoic acid (EPA)/icosapent ethyl (IPE) to statins in adults with hypertriglyceridemia (150-499 mg/dL) who have cardiovascular disease (CVD) or who are at increased risk of ASCVD.
8. Do NOT add EPA (IPE) in adults with severe hypertriglyceridemia (≥500 md/dL).
9. Do NOT use EPA plus docosahexaenoic acid (DHA) in addition to statin therapy in adults with hypertriglyceridemia (150-499 mg/dL) who have CVD or are at increased risk for CVD.
10. Insufficient evidence for or against the use of EPA plus DHA in adults with severe hypertriglyceridemia (≥500 md/dL).
11. Do NOT use niacin in addition to usual care in adults with hypertriglyceridemia (150-499 mg/dL) who have ASCVD or are at increased risk for ASCVD.
12. Insufficient evidence for or against the use of niacin in adults with severe hypertriglyceridemia (≥500 md/dL).
13. LDL-C treatment target of <70mg/dL in adults undergoing pharmacotherapy for dyslipidemia who have ASCVD or are at increased risk for ASCVD

References:

1. Patel SB, Wyne KL, Samina Afreen, et al. American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults With Dyslipidemia. Endocrine Practice. 2025;31(2). doi:https://doi.org/10.1016/j.eprac.2024.09.016