Clinical Policy: Enlicitide (Lipfendra)

Reference Number: CP.PHAR.807
Effective Date: 12.01.26
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Enlicitide (Lipfendra®) is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor.

FDA Approved Indication(s)

Lipfendra is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Cardiovascular outcomes trials have demonstrated that reducing LDL-C lowers the risk for major adverse cardiovascular events (MACE) in adults at increased risk when treated with statins or monoclonal antibody PCSK9 inhibitors as add-on to statin therapy.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Lipfendra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Primary Hypercholesterolemia (including HeFH) and Cardiovascular Event Risk Reduction (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. **HeFH**, and both of the following (i and ii):
      i. Baseline LDL-C ≥ 160 mg/dL (prior to any lipid-lowering pharmacologic therapy);
      ii. HeFH diagnosis is confirmed by one of the following (1 or 2):
         1) World Health Organization (WHO)/Dutch Lipid Network familial hypercholesterolemia diagnostic criteria score of > 8 as determined by requesting provider (*see Appendix D*);
         2) Definite diagnosis per Simon Broome criteria (*see Appendix D*);
   b. **Primary hypercholesterolemia that is not HeFH**, and both of the following (i and ii):
      i. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL;
      ii. Documentation of one of the following (1 or 2):

1) Presence of a genetically mediated form of primary hypercholesterolemia as evidenced by confirmatory genetic testing results;
2) A diagnosis of secondary hypercholesterolemia has been ruled out with absence of all of the following potential causes of elevated cholesterol (a-f):
   a) Poor diet;
   b) Hypothyroidism;
   c) Obstructive liver disease;
   d) Renal liver disease;
   e) Nephrosis;
   f) Medications that have had a clinically relevant contributory effect on the current degree of the member's elevated lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives;

c. **Increased risk for CV events** as evidenced by one of the following (i, ii, iii, or iv):
   i. Diabetes;
   ii. 10-year estimated risk for atherosclerotic cardiovascular disease (ASCVD) ≥ 10%;
   iii. Coronary artery calcium (CAC) score ≥ 100 to 299 Agatston units (AU);
   iv. History of ASCVD including any one of the following conditions (1-8):
      1) Acute coronary syndromes;
      2) Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging);
      3) CAC score ≥ 300 AU;
      4) Coronary or other arterial revascularization;
      5) Myocardial infarction;
      6) Peripheral arterial disease presumed to be of atherosclerotic origin;
      7) Stable or unstable angina;
      8) Stroke or transient ischemic attack (TIA);

2. Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist;
3. Age ≥ 18 years;
4. Failure of an 8-week trial of a preferred PCSK9 inhibitor*, if applicable, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;^
   ** Prior authorization may be required for PCSK9 inhibitors*
   ^ For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395
5. For members on statin therapy, both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
   a. Lipfendra is prescribed in conjunction with a statin at the maximally tolerated dose;
   b. Member has been adherent for at least the last 8 weeks to maximally tolerated doses of one of the following statin regimens (i or ii):
      i. A high intensity statin (*see Appendix E*);

ii. A moderate or low intensity statin (*see Appendix E*), and member has one of the following (1 or 2):
   1) Previous use of <u>one</u> high-intensity statin (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) for a minimum of 8 weeks continuously and LDL-C goal was not achieved;
   2) Member has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation;

6. For members <u>not</u> on statin therapy, member meets one of the following (a or b):*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
   a. Statin therapy is contraindicated per Appendix F;
   b. For members who are statin intolerant, both of the following (i and ii):
      i. Member has tried at least <u>two</u> statins, one of which must be hydrophilic (pravastatin, fluvastatin, or rosuvastatin);
      ii. Member meets one of the following (1 or 2):
         1) Member has documented statin risk factors (*see Appendix G*);
         2) Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
            a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
            b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
7. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 4 months, unless contraindicated per Appendix F or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
8. Documentation of recent (within the last 60 days) LDL-C of one of the following (a, b, or c):
   a. If member has history of ASCVD: ≥ 55 mg/dL;
   b. If member has HeFH, severe primary hypercholesterolemia with ASCVD risk factors (*see Appendix H*), or increased risk for CV events (not including history of ASCVD): ≥ 70 mg/dL;
   c. If member has severe primary hypercholesterolemia without ASCVD risk factors: ≥ 100 mg/dL;
9. Treatment plan does not include coadministration with Lerochol™, Leqvio®, Juxtapid®, Repatha®, or Praluent®;
10. Dose does not exceed 20 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Primary Hypercholesterolemia (including HeFH) and Cardiovascular Event Risk Reduction (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
3. Member is responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction since initiation of Lipfendra therapy;
4. Treatment plan does not include coadministration with Lerochol, Leqvio, Juxtapid, Repatha, or Praluent;
5. If request is for a dose increase, new dose does not exceed 20 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ASCVD: atherosclerotic cardiovascular disease
AU: Agatston units
CAC: coronary artery calcium
CHD: coronary heart disease
CV: cardiovascular
FDA: Food and Drug Administration
FH: familial hypercholesterolemia
HeFH: heterozygous familial hypercholesterolemia
LDL-C: low density lipoprotein cholesterol
PCSK9: proprotein convertase subtilisin kexin 9
SAMS: statin-associated muscle symptoms
TIA: transient ischemic attack
WHO: World Health Organization

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ezetimibe/simvastatin (Vytorin®)	10/40 mg PO QD	10 mg-40 mg/day (Use of the 10/80 mg dose is restricted to patients who have been taking simvastatin 80 mg for 12 months or more without evidence of muscle toxicity)
ezetimibe (Zetia®)	10 mg PO QD	10 mg/day
atorvastatin (Lipitor®)	40 mg PO QD	80 mg/day
rosuvastatin (Crestor®)	5 - 40 mg PO QD	40 mg/day
pravastatin	10 – 80 mg PO QD	80 mg/day
fluvastatin (Lescol®)	20 – 80 mg PO QD	80 mg/day
PCSK9 Inhibitors		
Praluent (alirocumab)	75 mg SC once every 2 weeks or 300 mg SC once every 4 weeks; if response to 75 mg every 2 weeks or 300 mg every 4 weeks is	300 mg/month

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	inadequate, dose may be increased to 150 mg once every 2 weeks	
Repatha (evolocumab)	140 mg SC every 2 weeks or 420 mg SC once monthly	420 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: Criteria for Diagnosis of HeFH

- Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia (FH)

FH Criteria	Points	Member's Score†
Family History		
First-degree relative with known premature* coronary and vascular disease	1	Place highest score here (0, 1 or 2)
First-degree relative with known LDL-C level above the 95th percentile	1	
First-degree relative with tendinous xanthomata and/or arcus cornealis	2	
Children aged < 18 years with LDL-C level above the 95th percentile	2	
Clinical History		
Patient with premature* coronary artery disease	2	Place highest score here (0, 1 or 2)
Patient with premature* cerebral or peripheral vascular disease	1	
Physical Examination		
Tendinous xanthomata	6	Place highest score here (0, 4 or 6)
Arcus cornealis prior to age 45 years	4	
Cholesterol Levels - mg/dL (mmol/liter)		
LDL-C ≥ 330 mg/dL (≥ 8.5)	8	Place highest score here (0, 1, 3, 5 or 8)
LDL-C 250 – 329 mg/dL (6.5 – 8.4)	5	
LDL-C 190 – 249 mg/dL (5.0 – 6.4)	3	
LDL-C 155 – 189 mg/dL (4.0 – 4.9)	1	
DNA Analysis		
Functional mutation in the *LDLR, apo B* or *PCSK9* gene	8	Place score here (0 or 8)
TOTAL SCORE	Definite FH: > 8	Place total score here __

*Premature – men < 55 years or women < 60 years

†Choose the highest score from each of the five categories and then add together for a total score. The five categories are 1) Family History, 2) Clinical History, 3) Physical Examination, 4) Cholesterol Levels, and 5) DNA Analysis.

- Simon Broome Register Group Definition of Definite FH (meets 1 and 2):
  1. One of the following (a or b):
     a. Total cholesterol level above 7.5 mmol/L (290 mg/dL) in adults or a total cholesterol level above 6.7 mmol/L (260 mg/dL) for children under 16
     b. LDL levels above 4.9 mmol/L (190 mg/dL) in adults (4.0 mmol/l in children) (either pre-treatment or highest on treatment)
  2. One of the following (a or b):
     a. Tendinous xanthomas in patient or relative (parent, child, sibling, grandparent, aunt, uncle)
     b. DNA-based evidence of an LDL receptor mutation or familial defective apo B-100

Appendix E: High, Moderate, and Low Intensity Daily Statin Therapy for Adults

High Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%***
• Atorvastatin 40-80 mg • Rosuvastatin 20-40 mg
Moderate Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%***
• Atorvastatin 10-20 mg • Fluvastatin XL 80 mg • Fluvastatin 40 mg BID • Lovastatin 40-80 mg • Pitavastatin 1-4 mg • Pravastatin 40-80 mg • Rosuvastatin 5-10 mg • Simvastatin 20-40 mg
Low Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by < 30%***
• Fluvastatin 20-40 mg • Lovastatin 20 mg • Pravastatin 10-20 mg • Simvastatin 10 mg

Appendix F: Statin and Ezetimibe Contraindications

Statins
• Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy) • Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment • Pregnancy*, actively trying to become pregnant, or nursing

Statins
• Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins
Ezetimibe
• Moderate or severe hepatic impairment [Child-Pugh classes B and C] • Hypersensitivity to ezetimibe (e.g., anaphylaxis, angioedema, rash, urticaria)

**In July 2021, the FDA requested removal of the contraindication against use of statins in pregnant women. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate. https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol*

Appendix G: Statin Risk Factors

Statin Risk Factors
• Multiple or serious comorbidities, including impaired renal or hepatic function • Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease • Concomitant use of drugs adversely affecting statin metabolism • Age > 75 years, or history of hemorrhagic stroke • Asian ancestry

Appendix H: ASCVD Risk Factors

ASCVD Risk Factors
• History of premature ASCVD in a parent or sibling (onset age < 55 years for men, < 65 years for women) • Higher risk ancestry (e.g., South Asian, Filipino) • High polygenic risk (if measured) • Chronic inflammatory diseases (e.g. systemic lupus, rheumatoid arthritis, advanced psoriasis, inflammatory arthritis) • Lp(a) ≥ 125 nmol/L or ≥ 50 mg/dL • hsCRP ≥ 2 mg/L on > 1 occasion (if measured) • TG persistently ≥ 175 mg/dL (2 mmol/L) (if nonfasting) and ≥ 150 mg/dL (1.7 mmol/L) (if fasting) • Cardiovascular-kidney-metabolic (CKM) syndrome • LDL-C persistently ≥ 160-189 mg/dL (4.1-4.9 mmol./L), non-HDL-C ≥ 190-219 mg/dL or apoB ≥ 120 mg/dL • Reproductive risk markers (premature menopause, preeclampsia, gestational diabetes, gestational hypertension, preterm delivery)

Appendix I: General Information

- Patients should remain on concomitant therapy with a statin if tolerated due to the established long term cardiovascular benefits.
- The diagnosis of SAMS is often on the basis of clinical criteria. Typical SAMS include muscle pain and aching (myalgia), cramps, and weakness. Symptoms are usually bilateral

and involve large muscle groups, including the thigh, buttock, back, and shoulder girdle musculature. In contrast, cramping is usually unilateral and may involve small muscles of the hands and feet. Symptoms may be more frequent in physically active patients. Symptoms often appear early after starting stain therapy or after an increase in dose and usually resolve or start to dissipate within weeks after cessation of therapy, although it may take several months for symptoms to totally resolve. Persistence of symptoms for more than 2 months after drug cessation should prompt a search for other causes or for underlying muscle disease possibly provoked by statin therapy. The reappearance of symptoms with statin rechallenge and their disappearance with drug cessation offers the best evidence that the symptoms are truly SAMS.

- Pravastatin, fluvastatin, and rosuvastatin are hydrophilic statins which have been reported to confer fewer adverse drug reactions than lipophilic statins.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypercholesterolemia (including HeFH)	20 mg PO QD	20 mg/day

VI. Product Availability

Tablet: 20 mg

VII. References

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Statin Tolerance

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.25.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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