Clinical Policy: Colesevelam (WelChol)

Reference Number: IL.ERX.PMN.250
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description
Colesevelam (WelChol®) packet for suspension is a bile acid sequestrant.

FDA Approved Indication(s)
WelChol is indicated as an adjunct to diet and exercise for:
Primary Hyperlipidemia
- To reduce elevated low density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia.
- To reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) if unable to reach LDL-C target levels despite an adequate trial of dietary therapy and lifestyle modification.

Type 2 Diabetes Mellitus
- To improve glycemic control in adults with type 2 diabetes mellitus.

Limitation(s) of use:
- WelChol should not be used for the treatment of type 1 diabetes or for treating diabetic ketoacidosis.
- The effect on cardiovascular morbidity and mortality has not been determined.
- WelChol has not been studied in type 2 diabetes in combination with a dipeptidylpeptidase 4 (DPP-4) inhibitor.
- WelChol has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.
- WelChol has not been studied in children younger than 10 years of age or in premenarchal girls.

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 Envolve Pharmacy Solutions that WelChol packet for suspension is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Primary Hyperlipidemia (must meet all)**:**
1. Request is for Welchol packet for suspension;
2. Prescribed for lipid lowering;
3. Age ≥ 10 years;
4. Documentation supports inability to swallow pills or clinically significant adverse effects to Welchol tablets;
5. Failure of cholestyramine powder for suspension at up to maximally indicated doses, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of ≥ 3 consecutive months of adherent use of a statin therapy, unless contraindicated or clinically significant adverse effect are experienced;
7. At the time of request, current (within the last 3 months) serum triglyceride concentrations do not exceed 500 mg/dL;
8. Dose does not exceed oral suspension packet of 3.75 grams (1 packet) per day.

Approval duration: 6 months

B. Type 2 Diabetes Mellitus (must meet all)**:**
1. Request is for Welchol packet for suspension;
2. Diagnosis of type 2 diabetes mellitus;
3. Age ≥ 18 years;
4. HbA1c drawn within the past 3 months is ≥ 6.5%;
5. Failure of adherent use of a triple anti-diabetic regimen which must include metformin in combination with agents from any of the following classes for ≥3 months, unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Glucagon-like peptide-1 (GLP-1) receptor agonist;
   b. Sodium glucose co-transporter 2 (SGLT-2) inhibitor;
   c. DPP-4 inhibitor;
   d. Thiazolidinedione (TZD);
   e. Basal insulin;
6. At the time of request, current (within the last 3 months) serum triglyceride concentrations do not exceed 500 mg/dL;
7. Dose does not exceed oral suspension packet of 3.75 grams (1 packet) per day.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed oral suspension packet of 3.75 grams (1 packet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DPP-4: dipeptidylpeptidase 4
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
HeFH: familial hypercholesterolemi
LDL-C: low-density lipoprotein cholesterol
SGLT-2: sodium glucose co-transporter-2
TZD: thiazolidinedione

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
colestipol (Colestid®)	**Primary Hyperlipidemia** Tablets: 2 g PO QD or BID Granules: 5 g PO BID	Tablets: 16 g/day Granules: 30 g/day
cholestyramine (Questran®, Prevalite®)	**Primary Hyperlipidemia** 4 g PO QD or BID	24 g/day
metformin (e.g., Fortamet®, Glucophage®)	**Type 2 Diabetes Mellitus** Immediate-release: 500 mg to 850 mg PO QD to BID, then titrate up to 2,000 mg/day Extended-release: 500 mg to 1,000 mg PO QD, then titrate up to 2,000 mg/day	Immediate-release: 2,550 mg/day Extended-release: 2,000 to 2,500 mg/day depending on the formulation
GLP-1 receptor agonist (e.g., Victoza®, Trulicity®, Byetta®)	**Type 2 Diabetes Mellitus** *Refer to prescribing information*	Refer to prescribing information
SGLT-2 inhibitor (e.g., Jardiance®, Invokana®, Farxiga®)	**Type 2 Diabetes Mellitus** *Refer to prescribing information*	Refer to prescribing information
DPP-4 inhibitor (e.g., Januvia®, Onglyza®, Nesina®)	**Type 2 Diabetes Mellitus** *Refer to prescribing information*	Refer to prescribing information
TZD (e.g., pioglitazone, Avandia®)	**Type 2 Diabetes Mellitus** *Refer to prescribing information*	Refer to prescribing information
Basal insulin (e.g., insulin glargine)	**Type 2 Diabetes Mellitus** Varies	Varies
HMG-CoA reductase inhibitors (aka statins) (e.g., atorvastatin, rosuvastatin, lovastatin, etc,)	**Type 2 Diabetes Mellitus** See Appendix D	Refer to prescribing information

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
- Contraindication(s):
  - Serum triglyceride concentrations > 500 mg/dL
  - History of hypertriglyceridemia-induced pancreatitis
  - History of bowel obstruction
- Boxed warning(s): none reported

Appendix D: High, Moderate, and Low Intensity Statins

High	Moderate	Low
atorvastatin 40-80 mg rosuvastatin 20-40 mg	atorvastatin 10-20 mg fluvastatin XL 80 mg fluvastatin 40 mg twice daily lovastatin 40 mg pitavastatin 2-4 mg pravastatin 40-80 mg rosuvastatin 5-10 mg simvastatin 20-40 mg	fluvastatin 20-40 mg lovastatin 20 mg pitavastatin 1 mg pravastatin 10-20 mg simvastatin 10 mg

Appendix E: Statin Contraindications
- 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
- 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Primary hyperlipidemia and type 2 diabetes mellitus	Oral suspension packets: 3.75 g PO QD	Packet: 3.75 g/day

VI. Product Availability
- Tablet: 625 mg
- Oral suspension packet: 3.75 g
- Chewable bar (chocolate, strawberry, caramel): 3.75 g

VII. References
1. Welchol Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo Inc.; July 2020. Available at: https://dsi.com/prescribing-information- portlet/getDocument?product=WC&inline=true. Accessed August 21, 2020.
2. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC Jr, Watson K, Wilson PWF. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Jul 1; 63(25 Pt B):2889-934
3. Garber AJ, Abrahamson MJ, Barzilay JI, Blonde L, Bloomgarden ZT, Bush MA, Dagogo- Jack S, DeFronzo RA, Einhorn D, Fonseca VA, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm—2017 executive summary. Endocr Pract. 2017; 23:207–38.
4. American Diabetes Association. Standards of medical care in diabetes—2019. Diabetes Care. 2019; 42(suppl 1): S1-S193.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.