

Clinical Policy: Colesevelam (WelChol)

Reference Number: HIM.PA.121

Effective Date: 12.01.17

Last Review Date: 11.19

Line of Business: HIM*

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

***For Health Insurance Marketplace members**, if request is through the pharmacy benefit, this policy applies only when the referenced drug is on the health plan approved formulary. Request for non-formulary drugs must be reviewed using the policy: HIM.PA.103.

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 Centene Corporation[®] 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 \geq 10 years;
4. Documentation supports inability to swallow pills or clinically significant adverse effects to Welchol tablets;
5. Failure of colestipol granules and cholestyramine powder for suspension at up to maximally indicated doses, each used for \geq 3 months, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of \geq 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 \geq 18 years;
4. HbA1c drawn within the past 3 months is \geq 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 \geq 3 months, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Glucagon-like peptide-1 (GLP-1) receptor agonist;
 - b. Sodium glucose co-transporter 2 (SGLT-2) inhibitor;
 - c. Dipeptidyl peptidase 4 (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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

- 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):

- 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

- Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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

- 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 – HIM.PHAR.21 for health insurance marketplace 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 hypercholesterolemia

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 <i>Refer to prescribing information</i>	<i>Refer to prescribing information</i>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
SGLT-2 inhibitor (e.g., Jardiance [®] , Invokana [®] , Farxiga [®])	Type 2 Diabetes Mellitus <i>Refer to prescribing information</i>	<i>Refer to prescribing information</i>
DPP-4 inhibitor (e.g., Januvia [®] , Onglyza [®] , Nesina [®])	Type 2 Diabetes Mellitus <i>Refer to prescribing information</i>	<i>Refer to prescribing information</i>
TZD (e.g., pioglitazone, Avandia [®])	Type 2 Diabetes Mellitus <i>Refer to prescribing information</i>	<i>Refer to prescribing information</i>
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	<i>Refer to prescribing information</i>

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 packets: 3.75 g
- Chewable bars (chocolate, strawberry, caramel): 3.75 g

VII. References

1. Welchol Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo Inc.; April 2019. Available at: <https://dsi.com/prescribing-information-portlet/getDocument?product=WC&inline=true>. Accessed August 13, 2019.
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	09.01.17	11.17
4Q 2018 annual review: removed references to oral tablet formulation of WelChol as it does not require prior authorization; added redirections to colesevelam tablets, colestipol granules, and cholestyramine powder for suspension per formulary status; simplified redirection to statins for lipid lowering indication; references reviewed and updated.	07.31.18	11.18
RT4: formulations and dosing: New FDA-approved chewable bar formulation added; the 1.875 oral suspension packet formulation is no longer available so is removed along with related dosing. Indication section updated per the package insert but with no related changes to the criteria: changes in the indication section include 1) removal of the parenthetical “Fredrickson Type IIa”	04.24.19	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
from primary hyperlipidemia, 2) removal of details around use of Welchol with or without a statin, 3) removal of specific lab (LDL-C) and family history requirements for HeFH, 4) under limitations of use, “do not use” changed to “should not use” regarding treatment of type 1 DM and DKA.		
4Q 2019 annual review: no significant changes; added for clarification that policy applies to packet for suspension only; references reviewed and updated.	08.13.19	11.19

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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