PCSK9 Inhibitors

Adjudication Guideline

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Daman	Pharmacy Standards & Governance	NA

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1. Abstract

1.1 For Members

PCSK9 inhibitors are a new class of lipid-lowering medications that are medically indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL- cholesterol (LDL -C).

1.2 For Medical Professionals

PCSK9 inhibitors are a new class of lipid-lowering medications that are administered as monthly or bimonthly subcutaneous injections. They are monoclonal antibodies to PCSK9, developed after the observation that naturally occurring loss-of-function polymorphisms resulting in PCSK9 under expression led to lower low-density lipoprotein cholesterol (LDL-C) levels.

Daman covers PCSK9 Inhibitors drugs according to medical necessity and as per policy terms and conditions for each health insurance plan administered by Daman.

2. Scope

This adjudication rule specifies the coverage details for medically necessary indications of PCSK9 inhibitors drugs as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Proprotein convertase subtilisin/kexin type 9 (PCSK9) is an enzyme produced in the liver. PCSK9 binds to the low-density lipoprotein receptor on the surface of hepatocytes, leading to its degradation and higher plasma LDL-cholesterol (LDL-C) levels. Blocking PCSK9 with antibodies leads to lower plasma LDL-C levels. Alirocumab and Evolocumab are fully humanized monoclonal antibodies that bind free plasma PCSK9. Inclisiran, interferes with RNA (genetic material) to limit the production of PCSK9.

Medication	Indications
Evolocumab	**Hypercholesterolaemia and mixed dyslipidaemia:** - As an adjunct to diet and exercise in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia. - In paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia (HeFH). - In combination with a statin or other lipid-lowering therapies if LDL-C goals are not reached with the maximum tolerated dose of a statin. - Alone or in combination with other therapies in patients who are statin-intolerant or for whom a statin is contraindicated. **Homozygous familial hypercholesterolaemia (HoFH):** - In combination with other lipid-lowering therapies for adults and paediatric patients aged 10 years and older. **Cardiovascular risk reduction:** - To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or revascularization) in adults at increased risk. - In adults with established atherosclerotic cardiovascular disease (ASCVD) to lower CV risk by reducing LDL-C levels, used with the maximum tolerated dose of a statin, with or without other therapies, or alone/in combination if statin is contraindicated or not tolerated

Medication	Indications
Alirocumab	**Hypercholesterolaemia and mixed dyslipidaemia:** - As an adjunct to diet in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia. - In paediatric patients aged 8 years and over with heterozygous familial hypercholesterolaemia (HeFH). - In combination with a statin or other lipid-lowering therapies if LDL-C goals are not reached with maximum tolerated dose. - Alone or in combination with other therapies in statin-intolerant or contraindicated patients. **Homozygous familial hypercholesterolaemia (HoFH):** - As an adjunct to diet and exercise to reduce LDL-C in adults unable to reach LDL-C goals with other treatments. **Cardiovascular risk reduction:** - In adults at increased risk for CV events, in patients unable to reach goals with maximum tolerated dose of other treatments. - In adults with established ASCVD to lower CV risk, used with maximum tolerated dose of a statin or alone/in combination if statin is contraindicated or not tolerated.
Inclisiran	**Hypercholesterolaemia and mixed dyslipidaemia:** - As an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including heterozygous hypercholesterolemia (HeFH) familial and non-familial, or mixed dyslipidaemia. AND - In adults unable to reach LDL-C goals with maximum tolerated dose of alternative treatments.

Dosage and administration:

Generic	Dose Strength	Dosage Form	Dose Frequency	Dose Optimizing
Evolocumab	140 mg/ml	SOLUTION FOR INJECTION	140 mg every two weeks, or 420 mg once monthly	420 mg every 2 weeks
Alirocumab*	75 mg/ml	SOLUTION FOR INJECTION	75 mg every 2 weeks	N/A
	150 mg/ml		150 mg every 2 weeks	
	300 mg/2ml		300 mg every 4 weeks	
Inclisiran	284 mg/1.5ml	SOLUTION FOR INJECTION	284 mg at week 0 284 mg at week 12 284 mg at week 24	N/A

For Alirocumab dosing:

*Patients less than 50 kg,150 mg every 4 weeks or 75 mg every 2 weeks
*Patients more than 50 kg, 300 mg once every 4 weeks or 150 mg every 2 weeks

3.2 Requirements for Coverage

- PCSK9 inhibitor drugs must evaluated properly.
- Eligible patients for PCSK9 inhibitors can be enrolled under Daman disease management program to ensure improve lifestyle.
- The disease management program aims to help patient to achieve goal of treatment and ensure healthy lifestyle.
- ICD and MOH codes must be coded to the highest level of specificity.

Eligible Clinician Specialty
Cardiology
Endocrinology
Internal medicine - Gastroenterology
Internal Medicine – interventional cardiology
Internal medicine - Nephrology

3.3 Non-Coverage

- As per policy terms and conditions for visitor's plan
- PCSK9 Inhibitors are not covered for basic plan as per non- availability in Basic Drug List PCSK9 Inhibitors will only be covered for the indications listed in the "Eligibility or Coverage Criteria".
- 2 boxes of Alirocumab 75 mg for dosage of 150mg will not be covered
- Patients less than 18 for medication Inclisiran
- Patients less than 10 for medication Evolocumab
- Patients less than 8 for medication Alirocumab

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

Questionnaire link:
https://www.damanhealth.ae/main/pdf/support/Questionnaire/QuestionairreFormfinal.pdf

4. Denial Codes

Code	Code Description
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender
Auth-001	Prior approval is required and was not obtained
CODE-010	Activity/diagnosis inconsistent with clinician specialty

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125522s033lbl.pdf
https://www.medicines.org.uk/emc/product/6962/smpc#gref
https://www.medicines.org.uk/emc/product/8093/smpc#gref
https://www.medicines.org.uk/emc/product/12039/smpc#gref
https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo
http://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125559Orig1s000lbledt.pdf
http://www.uptodate.com/contents/inherited-disorders-of-ldl-cholesterolmetabolism?source=machineLearning&search=Homozygous+Familial+Hypercholesterolemia&selectedTitle=1%7E150&sectionRank=1&anchor=H4#H4
http://www.uptodate.com/contents/search?search=Homozygous+Familial+Hypercholesterolemia+ 6.&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&searchOffset=
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Product_Information/human/003882/WC500194521.pdf
Repatha SureClick - Summary of Product Characteristics (SmPC) - (emc) | 6962
Praluent 150 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) | 8093
https://www.medicines.org.uk/emc/product/12039/smpc#gref
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125522s045lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125559s047lblcorrection.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/214012s016lbl.pdf

5.2 Revision History

Date	Version No.	Change(s)
22/08/2016	V1.0	Creation of Adjudication Guideline-External Instruction Template.
10/01/2023	V2.0	Questionnaire link update
28/10/2024	V3.0	Content update (Evolocumab and Alirocumab age update)
31/10/2025	V4.0	Update: A new indication has been added for each of Evolocumab, Alirocumab, and Inclisiran