PCSK9 Inhibitors

Adjudication Guideline

Rule Category:	Ref: No:	Version Control:	Effective Date:	Revision Date:
Pharmaceutical	2016-PH-001	Version No.5	22/09/2016	27/03/2026

Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmacy Standards & Governance	

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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

Daman covers all the types of PCSK9 drugs if medically indicated and as per policy terms and conditions for each health insurance plan administered by Daman.

Indications of Evolocumab:

- **Hypercholesterolaemia and mixed dyslipidaemia:**

  As adjunct to and exercise in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and in paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia **(HeFH)**, as below:

  - In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin **OR**
  - Alone or in combination with other lipid-lowering 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 paediatrics aged 10 years and older.

- **Reduction of cardiovascular risk in the following groups:**

- **Adults at increased risk:**

To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events.

- **Adults with established atherosclerotic cardiovascular disease (ASCVD):**

To lower cardiovascular risk by reducing LDL-C levels in adults with established atherosclerotic cardiovascular disease such as myocardial infarction, stroke or peripheral arterial disease, as an adjunct to correction of other risk factors as below:

◦ Used with the maximum tolerated dose of statin, with or without other lipid-lowering therapies

OR

◦ Used alone or with other lipid-lowering therapies in patients who are statin-intolerant or for whom a statin is contraindicated.

Indications of Alirocumab:

- **Hypercholesterolaemia and mixed dyslipidaemia:**

As adjunct to diet in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and in paediatric patients aged 8 years and over with heterozygous familial hypercholesterolaemia (HeFH), as below:

- In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin **OR**

- Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

- **Homozygous familial hypercholesterolaemia (HoFH):**

As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults.

- **Reduction of cardiovascular risk in the following groups:**

- Adults at increased risk:

To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events.

- **Adults with established atherosclerotic cardiovascular disease (ASCVD):**

  To lower cardiovascular risk by reducing LDL-C levels in in adults with established atherosclerotic cardiovascular disease, as an adjunct to correction of other risk factors as below:

  ◦ In combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies **OR**

  ◦ Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Indications of Inclisiran:

- **Hypercholesterolaemia and mixed dyslipidaemia:** As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous hypercholesterolemia (HeFH) familial and non-familial, or mixed dyslipidaemia.
- Patients more than 18 years old for medication Inclisiran

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

Hypercholesteremia classification :

Classifications	
Test	Range
LDL - C	Optimal: <1.8 mmol/L (<70 mg/dL) Desirable: 1.8 to <2.6 mmol/L (70-99 mg/dL) Near or above desirable: 2.6 to 3.3 mmol/L (100-129 mg/dL) Borderline high: 3.4 to 4.1 mmol/L (130-159 mg/dL) High: 4.1 to 4.9 mmol/L (160-189 mg/dL) Very high: ≥4.9 mmol/L (≥190 mg/dL)
Total Cholesterol	Optimal: <4.4 mmol/L (<170 mg/dL) Desirable: <5.2 mmol/L (<200 mg/dL) Borderline high: 5.2 to 6.2 mmol/L (200-239 mg/dL) High: ≥6.2 mmol/L (≥240 mg/dL)
Triglycerides	Ideal: <1.1 mmol/L (<100 mg/dL) Desirable: 1.1 to <1.7 mmol/L (100-149 mg/dL) Borderline high: ≥1.7 mmol/L (≥150 mg/dL) High: 2.3 to 5.6 mmol/L (200-499 mg/dL) Very high: ≥5.7 mmol/L (≥500 mg/dL)
HDL - C	Low: <1 mmol/L (<40 mg/dL)
Non- HDL - C	Non-HDL-C is considered high depending on the level of cardiovascular disease risk. low- to moderate-risk patients, high non-HDL-C: ≥3.7 mmol/L (≥145 mg/dL) high-risk patients, high non-HDL-C: ≥3.4 mmol/L (≥130 mg/dL) very high-risk patients, high non-HDL-C: ≥2.6 mmol/L (≥100 mg/dL)

2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines | Circulation

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

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/2022/125522s033lbl.pdf
https://www.medicines.org.uk/emc/product/6962/smpc#gref
https://www.medicines.org.uk/emc/product/8093/smpc#gref
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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
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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)
05/10/2025	V4.0	Update: A new indication has been added for each of Evolocumab, Alirocumab, and Inclisiran
27/03/2026	V5.0	Add Hypercholesteremia classification