

# PCSK9 Inhibitors Indications

## Adjudication Guideline

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Pharmaceutical

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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 diet 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 in adults and Pediatrics aged 10 years and older.
- **Homozygous familial hypercholesterolaemia:** In combination with other lipid-lowering therapies for adults and Pediatrics aged 10 years and older.
- **Established atherosclerotic cardiovascular disease:** 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 in adult patients

### Indications of Alirocumab:

- **Primary hypercholesterolaemia and mixed dyslipidaemia:** As adjunct to diet 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 in adults and Pediatrics aged 8 years and older.
- **Established atherosclerotic cardiovascular disease:** as an adjunct to correction of other risk factors 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:

- **Primary hypercholesterolaemia:** As an adjunct to diet 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 in adult patients.

### Dosage and administration:

Generic	Dose Strength	Dosage Form	Dose Frequency
Evolocumab	140 mg/ml	SOLUTION FOR INJECTION	140 mg every two weeks, or 420 mg once monthly
Alirocumab*	75 mg/ml	SOLUTION FOR INJECTION	75 mg every 2 weeks
	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

\*Patients less than 50 kg 150 mg every 4 weeks or 75 mg every 2 weeks

\*Patients more than 50 kg 150 mg once every 4 weeks or 150 mg every 2 weeks

## 3.2 Requirements for Coverage

- PCSK9 inhibitor drugs must be evaluated properly.
- Eligible patients for PCSK9 inhibitors can be enrolled under Daman disease management program to ensure improved lifestyle.
- The disease management program aims to help patients to achieve their goal of treatment and ensure a 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/QuestionnaireFormfinal.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.accessdata.fda.gov/drugsatfda_docs/label/2022/125522s033lbl.pdf)
- <https://www.medicines.org.uk/emc/product/6962/smhc#gref>
- <https://www.medicines.org.uk/emc/product/8093/smhc#gref>
- <https://www.medicines.org.uk/emc/product/12039/smhc#gref>
- [https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_Appr\\_ovalHistory#labelinfo](https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_Appr_ovalHistory#labelinfo)
- [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125559Orig1s000lbledt.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125559Orig1s000lbledt.pdf)
- <http://www.uptodate.com/contents/inherited-disorders-of-ldl-cholesterol-metabolism?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&searchOfset=](http://www.uptodate.com/contents/search?search=Homozygous+Familial+Hypercholesterolemia+6.&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&searchOfset=)
- [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_Product\\_Information/human/003882/WC500194521.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_Product_Information/human/003882/WC500194521.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)

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