



**Rule Category:**  
Pharmaceutical

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22-09-2016

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10-01-2023



## PCSK9 Inhibitors Indications

### Adjudication Guideline

#### Abstract

#### 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).

#### 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.

**Approved by:**  
Daman

**Responsible:**  
Medical Standards & Research

**Related Adjudication Guidelines:** NA

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## 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.

## Adjudication Policy

### 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.

- As per FDA Alirocumab and Evolocumab are medically indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults  $\geq 18$  years old with familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol (LDL - C).
- PCSK9 inhibitor drugs should be prescribed by Cardiologist or Endocrinologist specialty.
- The maximum approved dose of Alirocumab should not exceed 1 box of 150mg or 75 mg per 2 weeks.
- The maximum approved dose of Evolocumab should not exceed 420 mg once monthly.

### Requirements for Coverage

PCSK9 inhibitor drugs must go through authorization Department/ Case management for proper evaluation.

- 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.

### 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".
- Patient's age  $<18$  years old.
- 2 boxes of Alirocumab 75 mg for dosage of 150mg will not be covered

### 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>

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## 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

## Appendices

### A. References

- [https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#labelinfo](https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo)
- [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125559Orig1s0001bledt.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125559Orig1s0001bledt.pdf)
- <http://www.uptodate.com/contents/inherited-disorders-of-ldl-cholesterol-metabolism?source=machineLearning&search=Homozygous+Familial+Hypercholesterolemia&select>
- [edTitle=1%7E150&sectionRank=1&anchor=H4#H4](http://www.uptodate.com/contents/inherited-disorders-of-ldl-cholesterol-metabolism?source=machineLearning&search=Homozygous+Familial+Hypercholesterolemia&select#H4#H4)
- <http://www.uptodate.com/contents/search?search=Homozygous+Familial+Hypercholesterolemia+>
- [&sp=0&searchType=PLAIN\\_TEXT&source=USER\\_INPUT&searchControl=TOP\\_PULLDOWN&searchOf fset=](http://www.uptodate.com/contents/search?search=Homozygous+Familial+Hypercholesterolemia+&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&searchOf fset=)
- [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-](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)

### B. Revision History

Date	Change(s)
22-08-2016	Release of V1.0
10-01-2023	Questionnaire link update

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