Medicines Management Programme

Managed Access Protocol - Romosozumab for the treatment of severe osteoporosis

Medicine	Date of addition to Managed Access Protocol
Romosozumab (Evenity®)	01/11/2024

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved	Version 1.0	21/10/2024

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BMD	Bone Mineral Density
DXA	Dual-energy X-ray absorptiometry
HSE	Health Service Executive
HTH	High Tech Hub
Ig	Immunoglobulin
MAP	Managed Access Protocol
MOF	Major Osteoporotic Fracture
mg	Milligrams
MMP	Medicines Management Programme
PFP	Pre-filled Pen
PCRS	Primary Care Reimbursement Service
SD	Standard Deviations
SmPC	Summary of Product Characteristics

1. Romosozumab

Romosozumab (Evenity®) is a recombinant humanised immunoglobulin G2 (IgG2) monoclonal antibody that binds and inhibits sclerostin, thereby increasing bone formation due to the activation of bone lining cells, increasing bone matrix production by osteoblasts, and recruitment of osteoprogenitor cells. Additionally, romosozumab results in changes to expression of osteoclast mediators, thereby decreasing bone resorption.

From 1 November 2024, one presentation of romosozumab is available on the High Tech Arrangement for the treatment of severe osteoporosis:

- Evenity® 105 milligrams (mg) solution for injection in pre-filled pen (Evenity® 105 mg pre-filled pen [PFP])

1.1 Licensed indication

Romosozumab (Evenity®) is indicated in the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.

1.2 Reimbursement

Reimbursement of romosozumab on the High Tech Arrangement is supported only for a sub-group of the licensed population who meet the criteria outlined in this managed access protocol (MAP), i.e. women who are postmenopausal, with severe osteoporosis, who have experienced a major osteoporotic fracture (MOF) within the previous 24 months and who are at imminent risk of another fragility fracture. All criteria must be satisfied in order for reimbursement to be supported.

An application for reimbursement approval is required to be submitted on an individual patient basis through the online application system.

Table 1 outlines the licensed therapeutic dosage of romosozumab for the treatment of severe osteoporosis. Please refer to the Summary of Product Characteristics (SmPC) for further prescribing information.

Table 1 Licensed therapeutic dosage of romosozumab

Medicinal product (medicine)	Route	Dosage
Evenity® 105 mg solution for injection PFP (romosozumab)	Subcutaneous injection	210 mg (two PFPs) once monthly for 12 months

mg: milligrams, PFP: pre-filled pen

Evenity® is available on the High Tech Arrangement as a PFP, with one pack containing two PFPs. If a patient is recommended for reimbursement of romosozumab, reimbursement is supported in line with the licensed therapeutic dosage specified in Table 1, i.e. one pack of Evenity® (containing two PFPs) every month for a period of 12 months. Reimbursement of dosages in excess of the licensed therapeutic dosage (as outlined in Table 1) is not supported.

See Section 3 for further details on Reimbursement criteria – Requirement for outcome data.

1.3 Reimbursement price

The reimbursement price of the presentation of romosozumab available on the High Tech Arrangement is outlined in Table 2. A commercial-in-confidence arrangement is in place with the marketing authorisation holder to reduce the net acquisition cost of romosozumab to the Health Service Executive (HSE).

Table 2 Reimbursement code and price for the presentation of romosozumab available on the High Tech Arrangement

Medicinal product (pack size)	Code	Reimbursement Price*
Evenity® 105 mg PFP (2)	89347	€515.44

mg: milligrams; PFP: pre-filled pen
*Correct as at 01/11/2024

2. Reimbursement criteria

This section outlines the criteria that must be satisfied in order for patients to be recommended for reimbursement of romosozumab under the High Tech Arrangement.

2.1 Prescribers

Applications for reimbursement approval for romosozumab for the treatment of severe osteoporosis under the High Tech Arrangement will only be considered from consultants with specialist registration

with the Irish Medical Council in a specialism relevant to the management of osteoporosis (e.g. endocrinology, gerontology, rheumatology), and who have agreed to the terms of this MAP and been approved by the HSE ('approved consultants').

Approved consultants are responsible for ensuring that the patient or their representative/guardian is aware that the application for reimbursement approval is being made on their behalf.

The prescribing of Evenity® for approved patients for the treatment of severe osteoporosis under the High Tech Arrangement will be confined to approved consultants and their teams. The governance of the team on the High Tech Hub (HTH), including access, rests with the approved consultant.

2.2 Patient gender

Applications for reimbursement approval of romosozumab will only be considered for female patients.

2.3 Patient menstrual status

Applications for reimbursement approval of romosozumab will only be considered for patients who are post-menopausal at the time of application.

2.4 Patient diagnosis: Severe osteoporosis

Severe osteoporosis is defined as a bone mineral density (BMD) T-score that is 2.5 standard deviations (SD) or more below the young adult reference mean in the presence of one or more fragility fractures. Approved consultants are required to confirm a diagnosis of severe osteoporosis at the time of application.

For reimbursement to be supported, approved consultants are required to provide the relevant BMD T-score and the date of corresponding dual-energy X-ray absorptiometry (DXA) scan.

The BMD T-score, measured at the total hip, femoral neck or lumbar spine by DXA, must be 2.5 SD or more below the young adult reference mean. Alternatively, the distal forearm (1/3 radius) T-Score is acceptable if neither spine nor hip can be reliably measured or interpreted, or if a patient exceeds the weight limit for the DXA table.

2.5 Patient clinical history/status

2.5.1 Contraindications

In line with the SmPC for Evenity®, applications for reimbursement approval will not be considered for individuals who meet any of the contraindications for treatment as outlined in the SmPC.

2.5.2 Major osteoporotic fracture

Applications for reimbursement approval of romosozumab will only be considered for patients who have a history of a MOF in the 24-month period preceding the date of application.

A MOF is defined as a fracture of the hip, vertebrae, distal radius or proximal humerus. Approved consultants are required to provide evidence to validate that the MOF occurred in the 24-month period preceding the date of application, e.g. clinic letter, copy of patient notes, imaging report describing the MOF.

3. Reimbursement criteria – Requirement for outcome data

Follow-up data may be requested by the MMP for audit purposes and provision of same is a condition of ongoing reimbursement. It is the responsibility of the approved consultant to ensure that the patient or their representative/guardian is aware that the provision of follow-up data is a condition of reimbursement, and that audits may occur during which their personal data will be reviewed.

4. Prescribing of romosozumab for approved patients

Please refer to the SmPC for Evenity® for full prescribing information including monitoring and patient counselling requirements.

If a patient is recommended for reimbursement by the Health Service Executive-Medicines Management Programme (MMP), the High Tech prescription should be generated on the HTH. High Tech prescriptions that are not hub generated for romosozumab will not be eligible for reimbursement by the HSE-Primary Care Reimbursement Service (PCRS). Only approved consultants and their teams will have access to generate prescriptions.