Australian Government
Department of Health and Aged Care

Metal-backed patellae

Post-listing review report

March 2023

Contents

Abbreviations

AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
APP	All-polyethylene patellae
KPCAG	Knee Prostheses Clinical Advisory Group
MBP	Metal-backed patellae
PLAC	Prostheses List Advisory Committee
TGA	Therapeutic Goods Administration

Overview

Metal-backed patellae (MBP) have been subject to longstanding concerns about their high revision rates in comparison to all-polyethylene patellae (APP). Comparative data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) confirmed these concerns in the Australian context. Revision rates are a reliable marker of both safety and performance for many orthopaedic implants, including patellae.

For this reason, the former Prostheses List Advisory Committee (PLAC) recommended a post-listing review of MBP at its meeting on 12 May 2022.

The purpose of the review was to assess the comparative clinical effectiveness and cost-effectiveness of MBP compared to APP, and to inform decisions about the PL benefits for MBP on the Prostheses List (PL). MBP were noted to attract higher benefit amounts than APP, despite their apparently inferior safety and performance profile.

The Therapeutic Goods Administration (TGA) is conducting a parallel post-market-review of MBP, focusing on safety and performance. Any regulatory actions flowing from the TGA's post-market review will be considered for the implications for the PL settings by the department separately to this post-listing review.

The department published information about the PL Post-Listing Review Framework and the 4 initial review topics PLAC agreed to, including MBP devices, on the PL Reforms website in July 2022.

Items in scope for this review

This following MBP devices listed in groups 12.08.02 – Cemented, Polyethylene, Metal Backed and 12.08.03 – Uncemented, Polyethylene, Metal Backed on the PL as at July 2022 were in scope for this review:

- LCS Complete Knee System patella component (Cemented)
- ACS Knee System – Cemented mobile bearing patella (Cemented)
- RBK Total Knee System Patella component (Uncemented)
- LCS Complete Knee System patella component (Uncemented)
- ACS Knee System - Cementless mobile bearing patella (Uncemented)
- TC (Tri Compartment) PLUS Knee System and VKS Patella Component (Uncemented)
- Scorpio Knee System Patella Component (Uncemented)
- NexGen Patella Component (Uncemented)
- NexGen Trabecular Metal Augmented Patella (Uncemented)

Review process

The department conducted this review as an internal review, focusing on the comparative clinical effectiveness and cost effectiveness of MBP (noting TGA to be the lead agency regarding safety and performance).

The department invited MBP sponsors to provide an explanation to support higher benefits for MBP compared to APP, and to submit evidence that might suggest different conclusions around the comparative clinical performance of MBP than the AOANJRR data.

The department presented AOANJRR comparative data, sponsor submissions, and an outline of the department's policy position to the former Knee Prostheses Clinical Advisory Group (KP-CAG) for advice. KP-CAG advice was considered by the PLAC.

Methodology

In August 2022, the department engaged MBP sponsors to inform them about the review, and requested:

- Justification that demonstrates why your metal-backed patella should have higher benefit than all-polyethylene patellae (this may include a discussion of comparative clinical effectiveness and/or cost effectiveness); and
- Any available evidence that might contradict the AOANJRR data, which suggests inferior performance of MBP in comparison to APP. Specifically, evidence about superior patient outcomes, or patient subgroups for whom use was justified despite these apparent inferior outcomes.

A total of 4 submissions where received. Submissions were reviewed internally, noting explanations for the clinical circumstances in which MBP were considered by sponsors to be preferred over APP. Other sponsors indicated an intention to submit deletion applications for their PL-listed MBP devices.

The department then sought advice from the KPCAG on the current PL benefit amounts for MBP, noting higher benefits would be retained if:

- there was evidence of cost-effective superior clinical outcomes for MBP compared to APP; or
- clinical expert advice indicated that there were clinical subgroups/circumstances where MBP were the preferred option.

On 27 October 2022, the KP-CAG considered the submissions of all affected sponsors along with policy advice from the department. On 15 December 2022, the PLAC considered the review findings including the KP-CAG advice.

Findings and Analysis

The explanations provided by sponsors of when MBP use was indicated included:

- faster surgery time
- avoidance of cement (for reasons including cost, toxicity, allergy, abrasive properties of fragments)
- preferred option in younger people
- preferred option in heavier people (due to durability of cementless bone/implant interface)
- lower revision rates when used in hybrid constructs and in revision procedures.

On analysis of the sponsor submissions, the Department found that there was insufficient clinical evidence provided in sponsor submissions to verify the above claims. Hence it was decided that expert advice through the KPCAG would be required.

The KP-CAG determined that these explanations did not represent adequate justification for the use of MBP and concluded that there was insufficient evidence to support superior clinical outcomes for MBP, including for any clinical subgroups.

Some of the data provided was consistent with claims of non-inferiority for MBP, though with significant limitations due to sample size and methodology.

The KP-CAG advised that the information provided did not change their previous advice that all existing PL-listed MBP have inferior clinical outcomes to APP in (almost) any clinical setting. The only exception was that of bone-cement allergy, which was considered so rare that it did not warrant a specific PL action.

On 15 December 2022, the PLAC considered the review findings, including the KP-CAG advice and recommended that, based on available evidence, there should be no benefit difference between MBP and APP. That is, the PL benefit for MPP should be reduced to the PL benefit assigned to APP.

Conclusion

Based on the department's policy frameworks, a higher benefit amount for MBP would only be justified if there was evidence of cost-effective superior clinical outcomes of MBP compared to APP, or if clinical expert advice indicated that there were clinical subgroups/circumstances where MBP were preferred. Neither of these were found to apply to current MBP listed on the PL.

Recommendations

- The PLAC and the KP-CAG support a benefit reduction for MBP.
- Await the findings of the TGA's post-market review which may provide further insights and conclusions.

Outcome of the review

Following the PLAC's consideration, the Delegate confirmed support for the review's key recommendation to reduce benefits for MBP on the PL, to be consistent with benefits for APP.

No further action was required to finalise the outcome of this review, which formally concluded in March 2023.

Outcome of the post-listing review

To reduce the existing benefits for all metal-backed patellae listed on the Prostheses List. The new benefits were reflected in the March 2023 Prostheses List.