



Medical Services Advisory Committee

Public Summary Document

Application No.1134 – Injection of poly-L-lactic acid (Sculptra®) for the treatment of facial lipoatrophy caused by antiretroviral therapy in HIV positive patients

Applicant: Sanofi-aventis Australia Pty Ltd
Date of MSAC consideration: 46th MSAC meeting, 11 September 2009, Melbourne

1. Purpose of Application

In April 2009, Sanofi-aventis Australia Pty Ltd submitted an application to the Medical Services Advisory Committee (MSAC) seeking reimbursement for the procedure of injecting poly-L-lactic acid (Sculptra®) into HIV positive patients with severe facial lipoatrophy induced by antiretroviral therapy. The procedure was in association with an earlier application to the Pharmaceutical Benefits Advisory Committee (PBAC) in July 2008 for consideration at its November 2008 Meeting for the reimbursement of Sculptra® for the treatment of facial lipoatrophy induced by antiretroviral therapy in HIV positive patients.

2. Background

MSAC noted that PBAC had recommended poly-L-lactic acid on the basis of a high, but acceptable, incremental cost-effectiveness ratio. The committee was also advised that a notional Medicare Benefits Schedule (MBS) schedule fee for the professional service required in administration of poly-L-lactic acid had been included in PBAC modelling and that the cost effectiveness ratio was sensitive to this figure. MSAC was asked to comment on the basis for determining the schedule fee for injecting Sculptra, and on accreditation of the health professionals to administer the drug.

MSAC agreed that, as PBAC had completed and recommended poly-L-lactic acid for PBS listing on the basis of the cost-effectiveness of both the prescription and injection of the substance, a full MSAC technology evaluation was not required to provide advice on the medical service component of this treatment.

3. Clinical need

Highly active antiretroviral therapy (HAART) regimens have significantly improved survival and quality of life in patients with human immunodeficiency virus (HIV). However, one of the most distressing adverse effects of HAART is the development of facial lipoatrophy, in which facial volume loss alters the facial contours in the cheeks, temples and orbits, resulting in a characteristic emaciated appearance. Facial lipoatrophy has psychologically devastating consequences, including depression, anxiety, unintended disclosure of HIV status, social withdrawal/isolation, unemployment and non-compliance with therapy. Poly-L-lactic acid (Sculptra®) is a bio-active dermal stimulatory agent which reverses the visible effects of facial lipoatrophy and as a consequence impacts on the quality of life for HIV patients.

4. Summary of Consideration and Rationale for MSAC's Advice

- **Proposed approach to item descriptors to ensure consistency with PBS restrictions on indications for use** - MSAC noted that, according to the conditions of the PBS listing, the initial injection will be followed by a maximum of four subsequent adjustment treatments, and then one maintenance injection every two years. MSAC advised that the MBS item descriptors should reflect the PBS restrictions and limits.
- **Restriction to a particular group of prescribers** - MSAC noted that PBAC had agreed that the sponsor continue to manage the accreditation program, associated administrative records and limited distribution of the drug to company-approved prescribers to ensure competency for its injection into patients. MSAC further noted that accreditation is already a requirement within the PBS restriction, that there is no scope within Medicare to restrict items to trained practitioners unless formally endorsed by a professional Medical College and that it is difficult to allocate new speciality codes in Medicare systems.

- **List of comparable procedures** - MSAC noted that the comparable procedures to the injection of poly-L-lactic acid include current MBS items covering the deep injection of botulinum toxin and that maintenance injections were comparable to more superficial botulinum toxin injections. On this basis, MSAC recommended differentiating between the initial and subsequent injections of poly-L-lactic acid.
- **For the initial treatment** - MSAC agreed that the MBS items for the treatment of severe axillary hyperhidrosis by botulinum toxin injection (item 18362) for the treatment of spasmodic dysphonia by botulinum toxin injection (item 18368) and the fee for these items (\$227.90) are comparable with the skill level, complexity and time to initially administer poly-L-lactic acid.
- **For the subsequent treatments** - MSAC agreed that the MBS items for the treatment of hemi-facial spasm by botulinum toxin injection (items 18350 and 18351) and the fee for these items (\$115.35) are comparable with subsequent injections of poly-L-lactic acid (both the early adjustment treatments and the subsequent maintenance treatments every two years), which are not as complex or time consuming as the initial administration.
- **Appropriateness of suggested MBS fee** - MSAC considered the proposed approach for determining possible public funding of the initial and subsequent injections of poly-L-lactic acid as being clinically appropriate and agreed that the funding of each injection be set at the proposed schedule fees, with differentiation between the fee for initial and for subsequent injections.
- **Medicare Safety Net provisions** - MSAC considered that people with HIV (if eligible for treatment with poly-L-lactic acid) are likely to be over the Medicare Safety Net threshold, and that a substantial part of the cost of any co-payments charged by practitioners would therefore be borne by government through the Medicare Safety Net. Noting the PBAC modelling used to determine cost-effectiveness, MSAC agreed that overall government reimbursement should be limited to the scheduled fee, and requested that the Department also monitor practitioners' charging trends.

5. MSAC's Advice to the Minister

MSAC agreed that, based on the recommendations from PBAC regarding the prescription and injection of poly-L-lactic acid, a full MSAC technology assessment report is not required.

MSAC advised that two new MBS items be established for the administration of poly-L-lactic acid. MSAC further advised that the descriptors of both items should relate to the PBS restriction, with one relating to the initial injection and the other to all subsequent injections for a patient.

MSAC advised that the MBS fees should be set at \$227.90 for the initial injection and \$115.35 for all subsequent injections, and that the Medicare Safety Net provisions should not apply to charges above the MBS fee for these items.

MSAC advised that the Department should monitor utilisation and report back on charging trends after 12-18 months of listing.

6. Context for Decision

This advice was made under the MSAC Terms of Reference:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

7. Linkages to Other Documents

MSAC's processes are detailed on the MSAC Website at:

<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/evaluation-cycle-1>.