| **DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE AND USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
| --- | --- | --- | --- |
| **ELOSULFASE ALFA**  5 mg/5 mL injection, 5 mL vial  Vimizim®  Biomarin Pharmaceuticals Australia Pty Ltd  New listing  (Major submission) | Mucopolysaccharidosis  type IVA | Section 100 (Highly Specialised Drugs) listing for the treatment of mucopolysaccharidosis type IVA in patients who meet certain criteria. | The PBAC rejected the submission to list elosulfase alfa on the PBS as a Section 100 (Highly Specialised Drugs Program) benefit on the basis that a clear clinically significant clinical benefit with elosulfase alfa treatment had not been demonstrated and on the basis that the estimated incremental cost/QALY gained with elosulfase alfa treatment was unreliable but also unacceptably high.  On the basis of direct evidence presented by the submission, a patient treated with elosulfase alfa compared to placebo could expect an average improvement of 22.5 metres from their baseline 6MWT distance (the distance able to be walked in 6 minutes). However, this improvement could be as low as 4 metres or as high as 41 metres. A large number of patients are likely to experience an improvement of less than 20 metres.  On the basis of direct evidence presented by the submission, for every 100 patients treated with elosulfase alfa in comparison to placebo for 24 weeks:   * Approximately 12 additional patients will experience a serious adverse event. * Approximately 18 additional patients will experience a moderate to severe infusion associated reaction. * Approximately 19 additional patients will experience pyrexia. * Approximately 24 additional patients will experience vomiting. |
| Sponsor Comment: | BioMarin is disappointed with the PBAC outcome and will continue to work with the PBAC to make elosulfase alfa available for patients with MPS IVA |
| **ELTROMBOPAG**  tablets, 25 mg, 50 mg  Revolade®  GlaxoSmithKline Australia Pty Ltd  Change to listing  (Minor submission) | Decreased platelet count | Amend continuation restriction to allow continuation of treatment with eltrombopag in patients whose disease is stable and responding to treatment with romiplostim or vice versa. | The PBAC rejected the submission to amend the continuation restriction of eltrombopag for the treatment of severe chronic idiopathic thrombocytopenic purpura (iCTP) in adult patients to allow switching of treatment between eltrombopag and romiplostim beyond the initial 24 week treatment in patients whose disease is stable on the basis that the clinical effectiveness of eltrombopag and romiplostim was established on the 24 week initial treatment.  The PBAC considered that the clinical impact for patients who wish to switch treatment for reasons other than treatment failure is unclear and the cost-effectiveness and financial risk to government are unknown. |
| Sponsor Comment: | The sponsor will review the feedback contained in the minutes and consider its position regarding any future course of action. |
| **ITRACONAZOLE**  50 mg capsule, 60  Lozanoc®  Mayne Pharma International Ltd  New listing  (Minor submission) | Systemic fungal  infections | Authority Required (STREAMLINED) listing of a 50 mg capsule for the same indications as the currently PBS listed 100 mg capsule. | The PBAC rejected the submission to list itraconazole 50 mg on the PBS for the treatment of systemic mycoses as data demonstrating comparative efficacy and safety were not provided in the submission. In addition, the PBAC was concerned of the risk of prescriber and patient confusion with the currently listed itraconazole 100 mg and the therapeutic equivalence between the 50 mg and 100 mg capsules. |
| Sponsor Comment: | The sponsor strongly disagrees with the decision and is considering its position regarding any future course of action. The TGA approved Product Information (PI) states: that one capsule of LOZANOC 50 mg is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules; can be taken regardless of food and of gastric acid inhibitors; with less intra- and inter-subject variation in the extent of exposure than conventional itraconazole capsules. Given Lozanoc is the only 50 mg capsule of itraconazole available in Australia, and the Lozanoc PI highlights that Lozanoc and Sporanox are not interchangeable, the risk of prescriber and patient confusion is negligible. |
| **OCRIPLASMIN**  0.5 mg/0.2 mL injection, 1 x vial  Jetrea®  Alcon Laboratories (Australia) Pty Ltd  New Listing  (Major submission) | Vitreomacular traction | Authority Required listing for the treatment of vitreomacular traction including full-thickness macular hole in patients who meet certain criteria. | The PBAC did not recommend listing ocriplasmin for the treatment of vitreomacular traction (VMT) (including those with full-thickness macular hole (FTMH)) on the basis that cost-effectiveness of ocriplasmin is highly uncertain. The PBAC considered that it is unclear what effect ocriplasmin has on outcomes that are most relevant to patients, such as improving visual function and preventing, rather than delaying, vitrectomy in the long-term. Given that the effect on the patient relevant outcomes was not clear, the modelled evaluation was not considered to form a suitable basis for decision-making. |
| Sponsor Comment: | Alcon is committed to working with the PBAC to secure reimbursement of ocriplasmin for patient benefit. |
| **OXYCODONE**  10 mg modified release tablets  15 mg modified release tablets  20 mg modified release tablets  30 mg modified release tablets  40 mg modified release tablets  80 mg modified release tablets  OxyContin® MR  Mundipharma Pty Ltd  Change to listing  (Minor submission) | Chronic severe disabling pain | To amend the existing listing such that generic oxycodone tablets without a claimed abuse-resistant formulation cannot be substitutable with OxyContin by a dispensing pharmacist (i.e. not ‘a’ flagged). The submission further requests the PBAC consider quality use of medicines issues related to the listing of generic oxycodone tablets that do not have abuse-resistant formulation properties. | The PBAC did not agree to the submission’s request that the PBAC advise the Minister that generic oxycodone modified release tablets without crush deterrent formulation should not be ‘a’ flagged with OxyContin. The PBAC noted that it is usual practice for brands of the same pharmaceutical item which have been considered by the TGA to be bioequivalent to be ‘a’ flagged in the Schedule. The PBAC noted the Department’s advice that a note would be included in the PBS schedule from 1 December 2014 that makes the difference in the formulations clear and agreed this would assist prescribers to choose the most suitable product to meet the clinical needs of individual patients. The PBAC also noted input via the Consumer Comments facility on the PBS website and recognised the concerns raised regarding Quality Use of Medicines. The PBAC considered that removing ‘a’ flagging between OxyContin and other brands was not an appropriate mechanism to deal with the much broader problem of opioid medicines overuse. The PBAC advised that a systematic approach should be undertaken to review and target the use of these opioids to promote the Quality Use of Medicines. |
| Sponsor Comment: | Mundipharma is disappointed that the PBAC has limited its consideration of substitutability to the criterion of bioequivalence, when in it is not obliged to do so. If the objective of the PBAC is to assist prescribers to choose the most suitable product to meet the clinical needs of individual patients then a more prudent option would be to allow both products to be available on the PBS, but not to recommend an ‘a’ flag. This would ensure both that the prescribers have choice and that what gets dispensed matches their prescribing intention. It would also provide better protection to dispensing pharmacists. Mundipharma agrees that the problem of prescription opioid abuse requires a broad approach. No single initiative, however, can be expected to solve the problem in isolation. The National Prescription Opioids Abuse Framework for action, which has been ratified by the Commonwealth Government, includes a specific recommendation to ‘promote the use of tamper-resistant technologies for target medications’. Mundipharma believes that this recommendation represents a missed opportunity to support an important element of the Framework. |
| **PARACETAMOL**  665 mg tablet: modified release, 96 tablets  Paracetamol Osteo Tab®  AFT Pharmaceuticals Pty Ltd  New listing  (Minor submission) | Pain | Restricted Benefit listing for the relief of persistent pain associated with osteoarthritis. | The PBAC rejected the submission on the basis that no bioequivalence statement had been provided. In the absence of such a statement, the PBAC rejected the submission on the basis that no clinically relevant data had been presented to allow the PBAC to be sufficiently satisfied that the proposed product produces equivalent health outcomes as the existing product. |
| Sponsor Comment: | Sponsor noted the PBAC comments and is conducting further work to address them. |
| **RIOCIGUAT**  500 microgram tablet, 42 and 84  1 mg tablet, 42 and 84  1.5 mg tablet, 42 and 84  2 mg tablet, 42 and 84  Adempas®    Bayer Australia Ltd  New Listing  (Major submission) | Chronic thromboembolic pulmonary hypertension | Section 100 Authority Required listing for the treatment of chronic thromboembolic pulmonary hypertension. | The PBAC rejected the Authority Required listing for riociguat for the treatment of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension after a pulmonary endarterectomy, as the cost-effectiveness of riociguat for this indication had not been established against the appropriate comparator.  On the basis of direct evidence presented by the submission, treatment with riociguat, in comparison to placebo, over 16 weeks results in:   * An average increase of 46 metres in the distance able to be walked in 6 minutes. Both treatment groups were able to walk approximately 350 metres in 6 minutes at the beginning of the study. The PBAC has previously accepted for treatments of pulmonary arterial hypertension a minimum clinically important difference in 6MWD of between 35-50m. * An estimated 18 additional patients with an improvement by ≥1 WHO Functional class for every 100 patients. * An estimated 12 additional patients with dizziness for every 100 patients. * An estimated 8 additional patients with hypotension for every 100 patients. * An estimated 8 additional patients with headache for every 100 patients.   The PBAC was unable to establish the value for money of treating patients with the evidence provided in the submission. |
| Sponsor Comment: | Bayer is disappointed regarding the PBAC outcome, however Bayer will continue to work with the Department and the PBAC to progress riociguat towards reimbursement within Australia. |
| **UMECLIDINIUM BROMIDE + VILANTEROL TRIFENATATE (FDC)**  umeclidinium bromide 62.5 microgram/actuation + vilanterol trifenatate 25 microgram/actuation inhalation:  powder for    Anoro® Ellipta®    GlaxoSmithKline Australia Pty Ltd  Change to recommended listing    (Minor submission) | Chronic obstructive pulmonary disease | Amend recommended restriction to also include patients who have symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist and/or long acting beta2 agonist in addition to those already stabilised on a combination of a long acting muscarinic antagonist and long acting beta2 agonist. | The PBAC rejected the request to extend the current listing for umeclidinium with vilanterol to include patients with chronic obstructive pulmonary disease (COPD) who have symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA) and/or a long acting beta-2 agonist (LABA). The PBAC considered that the proposed restriction does not address the concerns raised by the PBAC when initially recommending umeclidinium with vilanterol for listing in that patients may initiate a fixed dose combination treatment before clinically appropriate. The PBAC reiterated its recommendation from the July 2014 meeting for the listing of umeclidinium with vilanterol. |
| Sponsor Comment: | GSK is disappointed with this outcome for COPD patients and considers the current restriction requiring stabilisation on a combination of a LABA and LAMA in separate inhalers prior to initiation of a fixed dose combination (FDC) to be unnecessarily burdensome on patients. The restriction may lead to patient confusion regarding correct inhaler use if patients have to use multiple inhaler types. Inhaler usage confusion may reduce patient adherence resulting in adverse efficacy and safety related consequences.  Furthermore COPD patients, many of whom are pensioners, will be required to pay two separate co-payments as opposed to one, had initiation of the FDC post monotherapy LABA or LAMA been permitted.  GSK will continue to engage with the PBAC to understand and address the issues raised. |
| **USTEKINUMAB**  45 mg/0.5 mL injection, 1 x 0.5mL vial  Stelara®  Janssen-Cilag Pty Ltd  Change to listing  (Major submission) | Psoriatic arthritis | Authority Required listing for the treatment of patients with severe active psoriatic arthritis who meet certain criteria. | The PBAC rejected a request to list ustekinumab as an Authority Required benefit for the treatment of psoriatic arthritis (PsA) on the basis of evidence of inferior effectiveness to adalimumab, particularly in terms of joint response, and a lack of compelling evidence of clinical need despite its different mechanism of action to the anti-TNF-α agents currently PBS listed for the treatment of PsA. |
| Sponsor Comment: | The sponsor had no comment. |