NOVEMBER 2018 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DENOSUMAB Injection 120 mg in 1.7 mL Xgeva® Amgen Australia Pty Ltd Change to listing (Minor submission)	Prevention of skeletal related events in patients with multiple myeloma and in patients with bone metastases from solid tumours.	DENOSUMAB is currently PBS listed for Giant cell tumour of bone, bone metastases from breast cancer or from castrate resistant prostate cancer, and osteoporosis in patients with a bone mineral density T-score of -2.5 or less.	Minor re-submission to request an extension of the current Section 85 Streamlined Authority Required listing for denosumab to include patients with multiple myeloma.	The PBAC did not recommend the PBS listing of denosumab for the treatment of multiple myeloma on the basis that the price proposal did not meet the requirements of a cost minimisation analysis.
			Comparator: Zoledronic acid and pamidronate	The PBAC accepted that zoledronic acid and pamidronate were appropriate comparators.
			Clinical claim: non-inferior comparative effectiveness for skeletal related events and similar safety.	The PBAC considered that the claim of non-inferior comparative effectiveness and similar comparative safety to zoledronic acid was reasonably supported by the data.
			Economic claim: cost-minimisation compared with either zoledronic acid or pamidronate, with cost-offsets for infusion costs.	The PBAC did not accept the approach taken in the cost-minimisation analysis. The PBAC noted the cost offsets associated with IV infusions of the comparators was substantially higher than the scheduled fees, as advised by the Medical Benefits Division. The latest Manual of resource items and their associated costs (version 5.0) specifies a preference for using only the relevant Medicare Benefits Schedule (MBS) fee if the medicine or medicinal preparation is administered by infusion.
			Sponsor's comments:	The sponsor had no comment.

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REGORAFENIB Tablet 40 mg (as monohydrate) Stivarga® Bayer Australia Ltd New listing (Major submission)	REGORAFENIB is indicated for the treatment of patients with: • Metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy. • Unresectable or metastatic gastrointestinal stromal tumours who progressed on or are intolerant to prior treatment with imatinib and sunitinib. • Hepatocellular carcinoma who have been previously treated with sorafenib.	REGORAFENIB is not currently PBS listed.	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Hepatocellular carcinoma (HCC) who have progressed on sorafenib treatment.	The PBAC did not recommend the listing of regorafenib for the treatment of hepatocellular carcinoma for patients who have progressed on first line treatment with a sorafenib on the basis that at the proposed price, the incremental cost-effectiveness ratio for regorafenib was unacceptably high.
			Comparator: Best supportive care (BSC).	The PBAC previously accepted that comparator of BSC.
			Clinical claim: superior to BSC, providing a statistically significant and clinically significant increase in overall survival but a higher incidence of adverse events.	The PBAC considered that regorafenib provided a modest survival benefit in some patients, however treatment was also associated with substantial toxicity.
			Economic claim: cost-effectiveness analysis compared with BSC.	The PBAC noted that the economic analysis presented in the resubmission addressed the majority of the PBAC's concerns, with the exception of the point of extrapolation. The PBAC considered that at the proposed price, the incremental cost-effectiveness ratio for regorafenib was unacceptably high.
			Sponsor's comments:	Bayer has proposed an ICER within the 45,000-75,000 ICER band, which we consider appropriate for an originally designated orphan population and recognized unmet need. Bayer also maintains its proposed restriction is consistent with the current available evidence and HTA principles.