

MARCH 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
<p>APREMILAST</p> <p>Tablet 30 mg Pack containing 4 tablets of 10 mg , 4 tablets of 20 mg and 19 tablets of 30 mg</p> <p>Otezla®</p> <p>Celgene Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> • signs and symptoms of active psoriatic arthritis in adult patients • adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy 	<p>APREMILAST is not currently PBS listed.</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe plaque psoriasis.</p>	<p>The PBAC did not recommend apremilast for the treatment of moderate to severe plaque psoriasis on the basis that the risk share arrangement (RSA) proposed by the sponsor was unlikely to achieve an overall price per patient for apremilast within the range the PBAC advised at its November 2017 meeting would be considered cost-effective.</p>
			<p>Comparator: Cyclosporin (November 2016 and subsequent resubmissions).</p>	<p>The PBAC previously accepted cyclosporin as the main comparator at its November 2016, March 2017 and November 2017 meetings. The submission did not nominate an alternative comparator.</p>
			<p>Clinical claim: Non-inferior comparative effectiveness and superior safety versus cyclosporin (November 2017 submission).</p>	<p>The PBAC previously considered at its November 2017 meeting that the claim of non-inferior efficacy was not well supported by the evidence presented in the submission, in particular noting the clinical heterogeneity of the trials included in the network meta-analysis (NMA). On balance, the PBAC considered the claim of non-inferior comparative effectiveness was likely to be reasonable.</p> <p>The PBAC previously considered at its November 2017 meeting that the claim of non-inferior safety in terms of adverse events was not reasonable and also considered the superiority claim for the safety profile overall was not well supported by the clinical evidence provided. However, noting the well-documented cumulative toxicity of cyclosporin and limitations of its therapeutic use in psoriasis to no more than two years, the PBAC considered the safety profile of apremilast was likely to be superior to cyclosporin.</p> <p>The minor submission did not make a new clinical claim.</p>

MARCH 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
			<p>Economic claim: Cost-minimisation basis with cyclosporin using a risk-sharing arrangement (RSA) to achieve an average cost-minimised price per patient (November 2017 submission).</p> <p>Sponsor's comments:</p>	<p>The PBAC previously considered at its November 2017 meeting that based on the uncertainty in the clinical data provided regarding non-inferior efficacy, but taking into account the reduced toxicity of apremilast compared to cyclosporin, the PBAC considered that a listing on a cost-minimisation basis (with offsets for reduced patient monitoring requirements) would likely be cost-effective for the purposes of the National Health Act 1953.</p> <p>The resubmission requested listing on a cost-minimisation basis with cyclosporin, achieved by means of an RSA proposal.</p> <p>The sponsor had no comment.</p>

MARCH 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
<p>ASFOTASE ALFA</p> <p>Injection 18 mg in 0.45 mL vial Injection 28 mg in 0.7 mL vial Injection 40 mg in 1 mL vial Injection 80 mg in 0.8 mL vial</p> <p>Strensiq®</p> <p>Alexion Pharmaceuticals Australasia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Enzyme replacement therapy in patients with paediatric-onset hypophosphatasia</p>	<p>ASFOTASE ALFA is not currently PBS listed.</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) listing for the treatment of patients with juvenile onset HPP (HPP; onset between the ages of 6 months and 17 years) who meet certain conditions.</p>	<p>The PBAC did not recommend the requested Section 100 (Highly Specialised Drugs Program) listing of asfotase alfa <i>rch</i> for the treatment of patients with juvenile-onset hypophosphatasia (HPP) on the basis of continuing uncertainty about the benefit of treatment in the juvenile onset population with this condition. However, the PBAC considered it is likely that there is a group of patients with HPP who would benefit most from treatment with asfotase alfa <i>rch</i> but that it was not possible to identify that group on the basis of the information provided in the current submission. The PBAC considered that the submission presented a high and very uncertain incremental cost-effectiveness ratio (ICER). The PBAC noted that asfotase alfa <i>rch</i> cannot be considered for the Life Saving Drugs Program (LSDP) for the treatment of juvenile-onset hypophosphatasia without PBAC being satisfied that it is clinically effective, but not cost-effective. However, the PBAC noted that asfotase alfa <i>rch</i> is currently being considered for inclusion in the LSDP for the treatment of the most severe forms of hypophosphatasia, perinatal- and infantile-onset disease.</p>
			<p>Comparator: Best supportive care</p>	<p>Accepted</p>
			<p>Clinical claim: Superior effectiveness and non-inferior safety compared with best supportive care.</p>	<p>The PBAC did not accept that asfotase alfa <i>rch</i> demonstrated superior effectiveness and non-inferior safety compared with best supportive care. The PBAC noted that no new clinical evidence was provided and the submission relied on one head-to-head randomised trial comparing asfotase alfa <i>rch</i> (n=13) with best supportive care (n=6), two supplementary non-randomised studies and a retrospective epidemiological review of patients receiving BSC. As with the original submission the PBAC considered the clinical evidence presented did not provide a strong estimate of the size of the benefit or a good indication of the likely variation</p>

MARCH 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
				<p>in the effect of treatment of asfotase alfa <i>rch</i> in the juvenile-onset HPP population.</p> <p>The PBAC considered that the incremental cost-effectiveness ratio (ICER) presented by the submission was unacceptably high and very uncertain.</p> <p>The PBAC again noted the basis of the economic model was improvement in the six minute walk test (6MWT). The PBAC considered this was not reasonable as there were no statistically significant differences observed between groups for this outcome in the randomised trial at 24 weeks. As for the previous submission, 6MWT may not be an acceptable surrogate outcome for patients with juvenile-onset HPP, particularly for those aged less than 5 years where 6MWT was not (and could not be) assessed in the trial or study. Further, the relationship between changes in 6MWT distance and changes in disease state severity was unclear as some symptoms experienced by patients with HPP are not related to the endurance measured by the 6MWT.</p>
<p>CLADRIBINE</p> <p>Tablet 10 mg</p> <p>Mavenclad®</p> <p>Merck Serono Australia Pty Ltd</p>	<p>Indication is for the treatment of relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical</p>	<p>Cladribine tablets are not currently PBS listed.</p>	<p>Resubmission to request an Authority Required listing for the treatment of relapsing remitting multiple sclerosis (RRMS).</p> <p>Comparator: The resubmission nominated fingolimod as the main comparator (unchanged).</p>	<p>Alexion is disappointed that a therapy which will address a clear unmet medical need is not been made available to juvenile-onset HPP patients with severe disability. Alexion nevertheless remains committed to work in partnership with the PBAC to find a workable solution to provide access to subsidised asfotase alfa for these patients.</p> <p>The PBAC did not recommend the listing of cladribine for the treatment of relapsing remitting multiple sclerosis (RRMS), on the basis of uncertainty in the non-inferior efficacy claim of cladribine versus fingolimod over two and four years.</p> <p>The PBAC accepted fingolimod as the appropriate main comparator, however considered that cladribine may replace or displace all PBS listed RRMS treatments.</p>

MARCH 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
New listing (Minor Submission)	disability. Following completion of the 2 treatment courses, no further cladribine treatment is required in years 3 and 4. Re-initiation of therapy after year 4 has not been studied.		Clinical claim: Non-inferior efficacy claim of cladribine versus fingolimod over two and four years (unchanged).	The PBAC noted the minor resubmission’s arguments for the use of the minimal clinically important differences (MCID) used in the ocrelizumab submission for RRMS (July 2017) in assessing the efficacy of cladribine, however it recalled that the Committee recommended ocrelizumab based on the totality of the evidence presented in that submission, and not on the basis of the proposed MCID. The PBAC noted that the minor resubmission did not address its concerns regarding the uncertainty in the non-inferior efficacy between cladribine and fingolimod over four years, or uncertainty in the non-inferior safety between cladribine and fingolimod. The PBAC therefore considered that the uncertainty in the non-inferior efficacy claim over two and four years, and non-inferior safety claim between cladribine and fingolimod, remained.
			Economic claim: Cost minimisation analysis based on a claim of non-inferior efficacy of 2 years’ treatment with cladribine to 4 years’ treatment with fingolimod (unchanged).	Given that the PBAC did not accept the claim that cladribine is non-inferior to fingolimod in terms of efficacy over four years, it did not accept this as the basis for estimating the equi-effective doses of cladribine and fingolimod, or as the basis for the financial analyses.
			Sponsor’s comments:	We are disappointed for the MS community that the Committee has been unable to recommend MAVENCLAD (cladribine tablets). Its dosing regimen of approximately 20 days treatment over 4 years is unique and fills an unmet need for a number of patients with RRMS. Merck appreciates the broad public support for MAVENCLAD as evidenced by the consumer comments received.

MARCH 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
<p>IRINOTECAN (NANOLIPOSOMAL)</p> <p>Injection concentrate for I.V. infusion 43 mg (as sucrosfate) in 10 mL</p> <p>Onivyde®</p> <p>Shire Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Indicated in the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil and folinic acid (leucovorin) in adult patients who have been previously treated with gemcitabine-based therapy.</p>	<p>IRINOTECAN (NANO-LIPOSOMAL) is not currently PBS listed.</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic pancreatic cancer in combination with 5-fluorouracil and folinic acid (5-FU/LV) in patients who have progressed following treatment with a gemcitabine based regimen.</p>	<p>The PBAC did not recommend the listing of irinotecan (in the form of I.V. injection containing nanoliposomal 43 mg in 10 mL, referred to as irinotecan (nanoliposomal)) in combination with 5-FU/folinic acid for the treatment of metastatic pancreatic adenocarcinoma in adult patients with disease progression who have previously received gemcitabine-based therapy. The PBAC based its decision on unacceptably high incremental cost-effectiveness in the context of a modest and uncertain incremental clinical benefit.</p>
			<p>Comparator: mFOLFOX6 (using 5-FU/folinic acid as a proxy).</p>	<p>Accepted.</p>
			<p>Clinical claim: Superior comparative efficacy and non-inferior safety compared with mFOLFOX6.</p>	<p>The PBAC considered the claim of superior efficacy was difficult to ascertain given the uncertainties associated with using a proxy treatment to determine the benefit of one treatment over another.</p> <p>The PBAC considered that irinotecan (nanoliposomal) is likely to be of similar safety to mFOLFOX6 and other oxaliplatin-containing regimens.</p>
			<p>Economic claim: Cost-effectiveness analysis compared with mFOLFOX6.</p>	<p>The PBAC noted that the submission presented a trial-based analysis comparing irinotecan (nanoliposomal) to mFOLFOX6 (using 5-FU/folinic acid as a proxy) which estimated a cost per life year gained (LYG).</p> <p>The PBAC considered it appropriate to incorporate quality of life into the analysis given the impact of the disease on quality of life is likely to be substantial. Overall, the PBAC considered that the estimated ICER was unacceptably high.</p> <p>The PBAC recommended that a resubmission should present a cost-minimisation analysis against alternative regimens used in the proposed setting.</p>
<p>Sponsor's comments:</p>	<p>The sponsor had no comment.</p>			

MARCH 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
<p>LENVATINIB</p> <p>Capsule 10 mg (as mesilate) Capsule 4 mg (as mesilate)</p> <p>Lenvima®</p> <p>Eisai Australia Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>LENVATINIB is indicated for the treatment of:</p> <ul style="list-style-type: none"> patients with progressive, locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer. (in combination with everolimus) adult patients with advanced renal cell carcinoma whose disease has progressed following one prior vascular endothelial growth factor targeted therapy. 	<p>LENVATINIB is currently PBS listed for the treatment of locally advanced or metastatic radioactive iodine refractory differentiated thyroid cancer.</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with advanced renal cell carcinoma following treatment with at least one anti-angiogenic therapy.</p>	<p>The PBAC did not recommend the listing of lenvatinib in combination with everolimus for the treatment of patients with stage IV clear cell variant renal cell carcinoma (RCC) on the basis that clinical need and clinical place in therapy were not adequately established.</p>
			<p>Comparator: cabozantinib.</p>	<p>The PBAC recalled that there were many established therapies for advanced RCC, and noted that cabozantinib was recommended for PBS listing at the December 2017 meeting. The PBAC noted the pre-PBAC response stated that lenvatinib/everolimus represents an alternative treatment option to cabozantinib. The PBAC considered that concerns regarding the magnitude of clinical benefit of lenvatinib/everolimus when compared to cabozantinib and other later line therapies meant that its clinical place in therapy was unclear. The PBAC re-affirmed that until the clinical place in therapy is established, an appropriate comparator for lenvatinib/everolimus cannot be determined.</p>
			<p>Clinical claim: Lenvatinib/everolimus is non-inferior in terms of effectiveness and safety compared with cabozantinib.</p>	<p>The PBAC considered that the claim of non-inferior effectiveness compared with cabozantinib, based on an indirect comparison, was inadequately supported by the evidence presented. In addition, the PBAC considered the claim of non-inferior safety to be uncertain, and considered it likely that lenvatinib/everolimus has a different safety profile compared with cabozantinib.</p>
			<p>Economic claim: cost-minimisation analysis compared with cabozantinib</p>	<p>The PBAC considered that a cost-minimisation analysis was inappropriate, as the indirect comparison evidence presented did not demonstrate non-inferior effectiveness for lenvatinib/everolimus compared with cabozantinib.</p>

MARCH 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
			Sponsor's comments:	Eisai Australia Pty Ltd nominated four comparators for lenvatinib+everolimus as a treatment for renal cell carcinoma: everolimus; nivolumab; cabozantinib and axitinib. Clinical evidence presented to the PBAC showed an increased duration of PFS and OS for lenvatinib+everolimus compared to all four comparators. As such, Eisai Australia Pty Ltd is disappointed that the PBAC is of the position that the clinical need was not adequately established and that claim of non-inferior effectiveness to cabozantinib was inadequately supported.
<p>LIRAGLUTIDE</p> <p>Injection 6 mg/mL, 3mL pre-filled pen</p> <p>Victoza®</p> <p>Novo Nordisk Pharmaceuticals Pty Limited</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Liraglutide is indicated as an adjunct to diet and exercise for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control:</p> <ul style="list-style-type: none"> • as monotherapy when metformin is contraindicated or is not tolerated • in combination with other glucose lowering medicines. <p>In patients where Liraglutide is indicated to improve glycaemic control, Liraglutide is indicated to reduce the risk of cardiovascular events in those at high cardiovascular risk, as an adjunct to standard</p>	LIRAGLUTIDE is not currently PBS listed.	<p>Resubmission to request a Special Pricing Arrangement (SPA) for liraglutide 1.2mg.</p> <p>Comparator: Exenatide</p> <p>Clinical claim: The submission claimed liraglutide 1.2 mg once-daily reduces the risk of cardiovascular events in adults with type 2 diabetes mellitus.</p>	<p>The PBAC advised the Minister that liraglutide 1.2 mg does not meet criteria 1 and 2 for a Special Pricing Arrangement for the treatment of patients with Type 2 diabetes mellitus (T2DM) at high risk of cardiovascular events. The PBAC has previously accepted that liraglutide 1.2 mg treats a significant medical condition and generates a substantial incremental benefit for the intended population over placebo. However, the PBAC considered that the submission did not provide sufficient evidence to support the claim that liraglutide 1.2mg has unique characteristics compared to any available alternative therapies, and noted that the medicine is recommended for listing in comparison with a medicine which does not have a similar arrangement.</p> <p>Accepted</p> <p>The PBAC did not accept that liraglutide 1.2 mg reduced the risk of cardiovascular events in adults with T2DM based on insufficient evidence presented in the minor submission. The PBAC acknowledged the TGA approval for this indication, but noted that this was in comparison to placebo. The PBAC recalled that at its July 2017 meeting, it considered an indirect comparison of</p>

MARCH 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
	of care therapy.			<p>liraglutide and exenatide including a full evaluation of the EXCEL trial patient characteristics and trial results was required to quantify how the cardiovascular benefits of liraglutide compared to exenatide.</p> <p>Economic claim: Not presented.</p> <p>Sponsor's comments:</p>
<p>SODIUM PHENYLBUTYRATE</p> <p>Granules 483 mg (as sodium) per g, 174 g</p> <p>Pheburane®</p> <p>Orpharma Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Indicated for the management of hyperammonaemia associated with urea cycle disorders. Pheburane® should be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, and protein-free calorie supplements)</p>	<p>SODIUM PHENYL-BUTYRATE is not currently PBS listed.</p>	<p>Resubmission to request an Authority Required listing for a sugar-coated granule formulation of sodium phenylbutyrate (referred to as 'coated NaPb') for the treatment of patients with urea cycle disorders (UCD).</p> <p>Comparator: The comparator nominated by the resubmission was uncoated NaPb powder compounded into an oral suspension or capsules by a compounding pharmacy.</p> <p>Clinical claim: Coated NaPb is non-inferior in terms of effectiveness and safety compared with compounded NaPb.</p> <p>Economic claim: Cost minimisation analysis versus compounded NaPb, i.e. uncoated NaPb powder that was compounded into oral suspension or capsules by a compounding pharmacy.</p>	<p>The PBAC did not recommend the listing of coated NaPb on the basis that cost-minimisation compared with other ammonia scavenger formulations was not adequately established.</p> <p>The PBAC recalled and re-iterated its November 2017 consideration, that sodium benzoate (an alternative ammonia scavenger) was also a relevant comparator for a proportion of patients in the monotherapy setting.</p> <p>The PBAC re-iterated its previous consideration that a claim of non-inferior comparative efficacy and safety compared with other ammonia scavenger formulations was appropriate given the clinical evidence that had been presented.</p> <p>The PBAC considered that the re-submission's cost-minimisation analysis significantly overestimated the cost of compounded NaPb because the analysis: excluded sodium benzoate as a comparator; included mark-ups, margins and compounding costs that were unreasonably high stating these were based on potential prices in the private market; and did not adequately</p>

MARCH 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
				justify the high level of wastage included. Overall, the PBAC considered that the cost-minimisation analysis did not reflect the cost of compounded ammonia scavengers that would be applicable under the PBS.
<p>TRIFLURIDINE WITH TIPIRACIL</p> <p>Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride)</p> <p>Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride)</p>	<p>Indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with, or are not considered candidates for, fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-</p>	<p>TRIFLURIDINE WITH TIPIRACIL is not currently PBS listed.</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer (mCRC).</p>	<p>The PBAC did not recommend the listing of trifluridine with tipiracil on the PBS for treatment of patients with metastatic colorectal cancer (mCRC) who have been treated previously or are not considered suitable for current available therapies. The PBAC based its decision on the modest clinical benefit and moderate toxicity, noting that the clinical benefit observed in the trial may not be realised in clinical practice. The PBAC noted the revised subsidisation caps proposed in the submission. However, the PBAC maintained that the impact of listing was substantial and represented a significant opportunity cost for the Commonwealth.</p>

MARCH 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
			Comparator: Best supportive care (BSC).	Accepted.
			Clinical claim: Superior efficacy and inferior safety of trifluridine/tipiracil compared with BSC.	There was no change to the clinical claim from the March 2017 resubmission. The PBAC previously accepted the claim of superior comparative effectiveness and inferior safety. However the PBAC considered the magnitude of benefit to be modest.
			Economic claim: Cost-utility analysis of trifluridine/tipiracil.	The PBAC noted that the base case economic evaluation was not substantially different from that of the previous submission. The PBAC considered that although the resubmission proposed revised expenditure caps set to half the estimated utilisation, there remained uncertainty in the estimated utilisation and therefore, it was uncertain whether these caps would be exceeded in practice. Therefore, the PBAC considered that it was unlikely that the ICER would be reduced through the proposed expenditure caps as proposed in the resubmission. For assessments of cost-effectiveness to rely on Risk Sharing Arrangement (RSA) rebates, the PBAC advised that it would need to have a high level of confidence in the utilisation estimates underpinning the RSA. As such, the PBAC considered that the proposed RSA was not an appropriate approach to achieve cost-effectiveness.
			Sponsor's comments:	The sponsor had no comment.