NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 38 draft remits and draft scopes and summary of comments and discussions at scoping workshops

	Batch 38
5.1	Ibrutinib for treating relapsed or refractory mantle cell lymphoma
5.2	Botulinum toxin type A for treating upper and lower limb spasticity associated with stroke
5.3	Pembrolizumab for treating advanced melanoma previously untreated with ipilimumab
5.4	Pembrolizumab for treating advanced melanoma previously treated with ipilimumab
5.5	Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia)
5.6	Evolocumab, ezetimibe and lomitapide for treating homozygous familial hypercholesterolaemia
5.7	Ramucirumab for treating advanced gastric cancer or gastro-oesophagel junction adenocarcinoma previously treated with chemotherapy

Provisional Title	Ibrutinib for treating relapsed or refractory mantle cell lymphoma		
Topic Selection ID Number	7051	**Wave / Round**	R85
TA ID Number	753		
Company	Janssen		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of ibrutinib within its licensed indication for treating relapsed or refractory mantle cell lymphoma.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ibrutinib for relapsed or refractory mantle cell lymphoma is appropriate The proposed remit is appropriate. No changes required <u>Population</u> It was agreed the population should be broadened to 'adults with relapsed or refractory mantle cell lymphoma', by removing 'who have received a prior rituximab-containing chemotherapy regimen', to reflect the wording of the positive opinion <u>Comparators</u> The following changes were agreed at the scoping workshop: - To state 'bortezomib containing chemotherapy regimens' rather than specify the combination - Addition of 'cytabarbine containing chemotherapy' and lenalidomide - Remove temsirolimus and SCT as a comparator <u>Innovation</u> Workshop attendees, including clinical experts and comparator manufacturers, all considered that this product was innovative and would lead to a step change in clinical management.		
Population size	The number of people diagnosed with mantle cell lymphoma is approximately 500 per year. This figure was confirmed in the scoping workshop. The proportion receiving treatment for relapsed and refractory disease will be less than this.		
Process (MTA/STA/HST)	STA		
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of ibrutinib within its **marketing authorisation** for treating relapsed or refractory mantle cell lymphoma.		
Costing implications of remit change	**Updated costing comments to reflect confirmed population of 500 diagnosed.** Ibrutinib is intended to be used as therapy for the treatment of relapsed or refractory mantle cell lymphoma (MCL). MCL is a rare, aggressive type of non-Hodgkin lymphoma (NHL) and comprises 5% of newly diagnosed cases of NHL. There were		

	10,789 cases of NHL in 2011, and approximately 500 cases of MCL. Of these patients, 30% have complete response to current treatments with the remaining 70% being eligible for ibrutinib. Patients are predominantly male and the peak age of diagnosis of MCL is 65 or over. Ibrutinib is administered orally at 560mg once daily. The cost of ibrutinib is unknown.
Timeliness statement	***CONFIDENTIAL INFORMATION REMOVED***

Provisional Title	Botulinum toxin type A for treating upper and lower limb spasticity associated with stroke		
Topic Selection ID Number	7266	**Wave / Round**	R101
TA ID Number	**768**		
Company	Allergan, Ipsen, Merz Pharma UK		
Anticipated licensing information	Botox, Dysport and Xeomin already have marketing authorisations for post-stroke spasticity in upper limbs. Botox already has a marketing authorisation for post-stroke spasticity in lower limbs. ***CONFIDENTIAL INFORMATION REMOVED*** Botox (Allergan) has a marketing authorisation in the UK for the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults and ankle disability due to lower limb spasticity associated with stroke in adults. Dysport (Ipsen) has a marketing authorisation in the UK for the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy. Xeomin (Merz Pharma UK) has a marketing authorisation in the UK for the treatment of post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults.		
Draft remit	To appraise the clinical and cost effectiveness of botulinum toxin type A preparations (Botox, Dysport, and Xeomin) within their licensed indication for treating upper and lower limb spasticity associated with stroke.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of Botulinum toxin type A for treating upper and lower limb spasticity associated with stroke is appropriate The proposed remit should be revised to reflect the marketing authorisation as follows: To appraise the clinical and cost effectiveness of botulinum toxin type A preparations (Botox, Dysport, and Xeomin) within their licensed indication for treating upper **or** lower limb **focal** spasticity associated with stroke. <u>Population and remit</u> - Concomitant use (for both upper and lower limb) is outside of the marketing authorisation. 'Treating upper *and* lower limb spasticity' implies concomitant use, therefore wording has been amended to *'or'* - Workshop attendees agreed that it was important to specify focal spasticity because the use of botulinum toxin type A preparations is not appropriate for non-focal spasticity. <u>Comparators</u> - The workshop agreed that drug treatment should be considered as an adjunct to physical therapy, and that 'physical therapy' was considered a more appropriate term than physiotherapy, as other physical treatments are also used.		

	- Workshop attendees heard that systemic medications were not used to manage focal spasticity and therefore were not appropriate comparators <u>Outcomes</u> The condition is very heterogenic and therefore finding common outcomes that are relevant to all patients is challenging. The workshop agreed to add the following: - Achievement of goals - Burden of care - Function (active and passive) The workshop attendees agreed to remove mortality as an outcome as spasticity itself does not impact mortality. <u>Subgroups</u> The workshop agreed that 'severity of stroke' and 'pattern of impact of stroke' were important in determining the effect of treatment and therefore should be added to the scope as subgroups.
Population size	In England, up to 41,800 people are affected by spasticity after stroke each year. Of the people who have spasticity associated with stroke, around 33,000 people have upper limb spasticity and around 27,600 people have lower limb spasticity. Around 25,000 people will have spasticity in both upper and lower limbs.
Process (MTA/STA/HST)	MTA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of botulinum toxin type A preparations (Botox, Dysport, and Xeomin) within their **marketing authorisations** for treating upper **or** lower limb **focal** spasticity associated with stroke.
Costing implications of remit change	Updated costing comments based on applicable population of around 60,000 Stroke is the third biggest cause of death in the UK and the largest single cause of severe disability. In England, approximately 110,000 people will have a stroke each year and around 30,000 of these will go on to have a further stroke. Spasticity is a common symptom following a stroke and usually occurs within the first few days or weeks, although the timing of onset can be highly variable. Around 33,000 people have upper limb spasticity and around 27,600 people have lower limb spasticity indicating a potential eligible population of around 60,000 people There are three preparations of botulinum toxin type A that have marketing authorisations for treating upper or lower limb focal spasticity associated with stroke – Botox, Dysport and Xeomin. The cost of the preparations varies with Botox costing £276.40 for a 200 unit vial and Dysport costing £154 for a 500 unit vial. In clinical trials for this indication , botulinum toxin type A was administered via intramuscular (IM) injection at 300 units (u) on day 1, with an optional 100u, IM injection into additional lower

	limb muscles followed by 400u up to 3 times every 12 weeks over a 42 week period. Based on this regimen the annual drug cost per person may be up to £2,000-£7,200 depending on the preparation used. It is not known how many people will be suitable for treatment and what the likely uptake would be. Using a midpoint of the upper cost range of £4,600, this topic would be high cost if around 3,260 people received treatment with botulinum toxin type A before taking into account savings from other treatment options avoided. There is potential for this topic to be high cost.
Timeliness statement	Given that marketing authorisations have already been received for all of these technologies, issuing timely guidance will not be possible.

Provisional Title	Pembrolizumab for treating advanced melanoma previously untreated with ipilimumab		
Topic Selection ID Number	7139	**Wave / Round**	R82
TA ID Number	801		
Company	Merck Sharp & Dohme		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of pembrolizumab within its licensed indication for treating advanced melanoma in people previously untreated with ipilimumab		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pembrolizumab for treating advanced melanoma previously untreated with ipilimumab is appropriate. The scoping workshop attendees discussed the population and noted that patients could have received more than 1 prior therapy other than ipilimumab and so the proposed population should not be restricted to those who have received only 1 prior line of therapy. The scoping workshop attendees agreed that the correct population for this proposed appraisal should be 'People with advanced (unresectable stage III or stage IV) melanoma previously untreated with ipilimumab'. The scoping workshop attendees discussed the comparators, in particular whether dacarbazine should be included. They noted that dacarbazine is still used in some patients for first and subsequent lines of treatment in order to get symptomatic benefits and therefore should be considered as a comparator. The scoping workshop attendees noted that temozolomide is not used in clinical practice for treating advanced melanoma in people with brain metastases and therefore they agreed that it should not be considered a comparator for pembrolizumab. The scoping workshop attendees also considered that if dabrafenib receives a positive recommendation from NICE, it will be used in the same place in the treatment pathway as vemurafenib. The comparators in the scope have been amended to reflect the comments from consultees as follows: • dacarbazine • ipilimumab • vemurafenib (for people with BRAF V600 mutation-positive disease) • dabrafenib (for people with BRAF V600 mutation-positive disease) At the Decision Point 4 meeting, attendees agreed that a single referral should be sought for this proposed appraisal and the proposed appraisal of Pembrolizumab for treating advanced melanoma previously treated with ipilimumab [ID 760] (see item		

	5.4). The title of the appraisal will be pembrolizumab for treating advanced melanoma.
Population size	There were 11,121 people diagnosed with melanoma in England in 2011, of whom around 10% had advanced (unresectable or metastatic) melanoma.
Process (MTA/STA/HST)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of pembrolizumab within its **marketing authorisation** for treating advanced melanoma
Costing implications of remit change	Pembrolizumab is intended for the treatment of advanced melanoma. The incidence of malignant melanoma in the UK has more than quadrupled over the last 30 years. Malignant melanoma is the less common, but more serious type of skin cancer, representing approximately 4% of all cancers. In 2011, 11,121 people were diagnosed with malignant melanoma, 10% (around 1,100) had metastatic or unresectable melanoma. Using the costing template for TA268 (Melanoma (stage III or IV) - ipilimumab) it is estimated that of the 1,100 people, 70% were suitable to receive chemotherapy / active treatment and only 20% (around 160 people) were eligible for ipilimumab. Therefore around 620 people are not eligible for treatment with ipilimumab and may receive treatment with pembrolizumab either first or second line. The uptake of pembrolizumab is not known. Other treatment options are available. In clinical trials pembrolizumab was administered by intravenous (IV) infusion at 2mg/kg every 3 weeks or at 10mg/kg every 3 weeks. The cost of pembrolizumab is not yet known but due to a small population and it being an additional treatment option, it is considered that this topic has potential to be low cost.
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Pembrolizumab for treating advanced melanoma previously treated with ipilimumab		
Topic Selection ID Number	7029	**Wave / Round**	R82
TA ID Number	760		
Company	Merck Sharp & Dohme		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of pembrolizumab within its licensed indication for treating advanced melanoma in people whose disease is refractory to ipilimumab.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pembrolizumab for treating advanced melanoma previously treated with ipilimumab is appropriate. The population should be amended since the scoping workshop attendees noted comments from consultation highlighting that the term 'refractory' was ambiguous and open to different interpretations. They noted that the main criterion that differentiates this indication from the other one was previous treatment with ipilimumab. They agreed that the term refractory should be removed and the population amended to "People with advanced (unresectable stage III or stage IV) melanoma whose disease has progressed after previous treatment with ipilimumab" Attendees at the scoping workshop discussed the comparators for pembrolizuamb and they suggested that vemurafenib and dabrafenib should be included as comparators in the scope. It was noted that vemurafenib could be used second line and if dabrafenib receives a positive recommendation from NICE, it will be used in the same place in the treatment pathway as vemurafenib. The comparators have been amended to: • dacarbazine • vemurafenib (for people with BRAF V600 mutation-positive disease) • dabrafenib (for people with BRAF V600 mutation-positive disease) • best supportive care At the Decision Point 4 meeting, attendees agreed that a single referral should be sought for this proposed appraisal and the proposed appraisal of pembrolizumab for treating advanced melanoma previously untreated with ipilimumab [ID801] (see item 5.3). The title of the appraisal will be pembrolizumab for treating advanced melanoma.		

Population size	There were 11,121 people diagnosed with melanoma in England in 2011, of whom around 10% had advanced (unresectable or metastatic) melanoma
Process (MTA/STA/HST)	N/A – will be combined with item 5.3
Proposed changes to remit (in bold)	N/A – will be combined with item 5.3
Costing implications of remit change	N/A – will be combined with item 5.3
Timeliness statement	N/A – will be combined with item 5.3

Provisional Title	Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia)		
Topic Selection ID Number	6637	**Wave / Round**	R62
TA ID Number	765		
Company	Amgen		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of evolocumab within its licensed indication for hyperlipidaemia and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia).		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of evolocumab for hyperlipidaemia and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia) is appropriate. The proposed remit should be amended. Scoping workshop attendees suggested that the term 'hyperlipdaemia' was non-specific and that it overlapped with 'mixed dyslipidaemia' as both terms could include elevated triglyceride levels. Scoping workshop attendees suggested that the remit should be amended to reflect the proposed marketing authorisation as follows: To appraise the clinical and cost effectiveness of evolocumab within its licensed indication **for treating primary hypercholesterolaemia (heterozygous familial and non-familial)** and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia).At the Decision Point 4 meeting, it was agreed that '...(excluding homozygous familial hypercholestrolaemia)' was no longer required in the remit as it was clear that this population was excluded. The population should be amended in line with the revised remit to 'people with primary hypercholesterolaemia (heterozygous familial and non-familial) and mixed dyslipidaemia (excluding homozygous familial hypercholesterolaemia) for whom lipid-modifying therapies would be considered in line with current NICE guidance'. At the Decision point 4 meeting it was agreed that '..(excluding homozygous familial hypercholesterolaermia)'' should be removed in line with the amended remit. The intervention should be amended to reflect its likely use in clinical practice. Clinical experts explained that it would not be reasonable to expect that evolocumab would be used alone as an initial treatment option in place of statins and that it would likely be used if the target response could not be achieved with statins alone or statins and ezetimibe. Scoping workshop attendees suggested that the intervention should be amended as follows: • Evolocumab in combination with a statin • Evolocumab in combination with a statin and ezetimibe		

	• Evolocumab alone or in combination with ezetimib when statins are contraindicated or not tolerated) (*note that the interventions suggested by the scoping workshop attendees are more restrictive than the wording of the proposed marketing authorisation*) The comparators should be amended by removing statins, nictonic acid, fibrates and bile acid sequestrants. Scoping workshop attendees agreed that statins should be removed as a comparator because it is anticipated that evolocumab will be added to background statin therapy for those on optimal statin therapy and whose LDL-C is not adequately controlled and statins would not be an appropriate comparator for those people who are statin intolerant or for whom a statin is not considered clinically appropriate. Scoping workshop attendees also agreed that nictonic acid, fibrates and bile acid sequestrants should be removed as comparators as they have not been recommended in NICE clinical guideline 181 and were not considered as established clinical practice in England. At the Decision point 4 meeting it was agreed that the following comparator 'Ezetimibe in combination with a statin (when initial statin therapy does not appropriately control LDL- cholesterol)'should be amended to 'Ezetimibe in combination with a statin (when **optimised** statin therapy does not appropriately control LDL-cholesterol) to reflect the recommendation in NICE clinical guideline 181. The outcome measures should be amended to include non - HDL-C and 'the requirement of procedures including LDL aspheresis and revascularisation'. Scoping workshop attendees noted that NICE clinical guideline 181 recommends routine measurement of non-HDL-C (instead of LDL-C) to guide lipid lowering treatment and that measurement of non-HDL-C is available in routine clinical practice and is increasingly being used. The company stated non-HDL-C was a secondary outcome measure in the trials. Scoping workshop attendees agreed that reducing the need for apheresis would be valued by people with very high levels of LDL-C as well as by clinicians. Attendees also agreed that the ultimate aim of lipid lowering therapy is to prevent cardiovascular disease and therefore the need for revascularisation is an important outcome. If evidence allows, the following subgroups should be added: • Presence or risk of cardiovascular disease • Patients with heterozygous familial hypercholesterolaemia. Scoping workshop attendees agreed that people with heterozygous familial hypercholesterolaemia are a distinct patient population and should be considered separately from those with non-familial hypercholesterolaemia and mixed dyslipidaemia. • Patients with statin intolerance. Attendees heard that people with statin intolerance were treated with ezetimibe monotherapy and that evolocumab could be particularly valuable to them. • Severity of hypercholesterolaemia. Attendees agreed that

	treatment options may vary depending on the severity of baseline cholesterol levels, and evolocumab may be reserved for patients with a very high level of LDL-C.
Population size	Heterozygous familial hypercholesterolaemia diagnosed: 16,000-18,000 Primary non-familial hypercholesterolaemia receiving treatment: 460,000 Mixed dyslipidaemia: presumably very large population
Process (MTA/STA/HST)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of evolocumab within its **marketing authorisation** for **treating primary hypercholesterolaemia (heterozygous familial and non-familial**) and mixed dyslipidaemia
Costing implications of remit change	It is estimated that the eligible population for this topic may be from two groups: a population of at least 10,000 people who have contraindications or intolerance to statins, and at least a further 141,000 who may experience an adverse effect, or poor response from a statin, and to be switched to any of the alternative treatments. The proportion of this total population of around 150,000 who will receive evolocumab is unknown. Evolocumab represents an additional treatment option for and is intended for use alone or in combination with another statin. Evolocumab is administered by subcutaneous injection whereas comparators tend to be orally administered. The different administration route may affect uptake. The unit cost of Evolocumab is also unknown, so the cost impact cannot currently be estimated. Savings or costs associated with the efficacy of the treatment cannot be quantified at this stage.
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Evolocumab, ezetimibe and lomitapide for treating homozygous familial hypercholesterolaemia		
Topic Selection ID Number	4248	**Wave / Round**	N/A
TA ID Number	810		
Companies	Amgen (evolocumab), Merck, Sharp and Dohme (ezetimibe), Aegerion Pharmaceuticals (lomitapide)		
Anticipated licensing information	Evolocumab • does not currently have a marketing authorisation in the UK. ***CONFIDENTIAL INFORMATION REMOVED***. Ezetimibe • has a marketing authorisation in the UK when co-administered with a statin as adjunctive therapy to diet for use in patients with homozygous familial hypercholesterolaemia. Patients may also receive adjunctive treatments (for example, LDL aspheresis). Lomitapide • has a marketing authorisation in the UK for use as an adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein apheresis in adult patients with homozygous familial hypercholesterolaemia. ***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of evolocumab, ezetimibe and lomitapide within their licensed indications for treating homozygous familial hypercholesterolaemia		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of evolocumab , ezetimibe and lomitipide for treating homozygous familial hypercholesterolaemia is **not** appropriate. Scoping workshop attendees noted the following: • homozygous familial hypercholesterolaemia (HoFH) is a very rare condition. • Resource impact was not expected to be high. • Limited data available and therefore robust indirect comparisons and cost-effectiveness analyses were unlikely. • The company manufacturing lomitapide highlighted that previously Topic Selection had decided not to proceed with lomitipide because it was licensed for patients with HoFH which is a rare condition.		
Population size	50-60 people with HoFH have been identified in the UK, although the clinical experts at the scoping workshop stated that some people remain undiagnosed and the actual number could be 180.		
Process (MTA/STA/HST)	– N/A – A referral is not sought		
Proposed changes to remit (in bold)	N/A – A referral is not sought		
Costing	The cost of evolocumab is not yet known for this indication. The		

implications of remit change	cost of ezetimibe 10 mg daily is £26 for 28 days (annual cost of almost £350). The cost of lomitapide is £17,765 for a 28 day supply (5 mg, 10 mg or 20 mg). The suggested dose is 5 mg-60 mg daily. Assuming an average dose of 20 mg is taken on an ongoing basis, the estimated annual cost per person is around £230,000. Based on 60 people in the UK diagnosed with HoFH (around 50 in England), the topic will be low cost if the total cost per person across the three drugs is less than £300,000
Timeliness statement	N/A – A referral is not sought

Provisional Title	Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy		
Topic Selection ID Number	7038/7228	**Wave / Round**	R84 & R96
TA ID Number	**741**		
Company	Lilly		
Anticipated licensing information	Positive opinion received in September 2014 • Ramucirumab in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. • Ramucirumab monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate.		
Draft remit	To appraise the clinical and cost effectiveness of ramucirumab within its licensed indication for advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ramucirumab within its licensed indication for advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy is appropriate. The proposed remit is appropriate. No changes are required. The population in the scope should be amended to include a second population. At the scoping workshop, the attendees agreed that no changes to the population in the draft scope were needed at that time. However, CHMP positive opinion for monotherapy and combination therapy was issued 3 weeks after the scoping workshop, and therefore the NICE technical team suggest that the following population should be added to the scope: 'Adults with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy for whom treatment with ramucirumab in combination with paclitaxel is not appropriate'. The comparators in the scope should be amended to include FOLFIRI and best supportive care defined as 'including anti-emetics, stents and blood transfusions'.		
Population size	Approximately 4,300 people diagnosed with metastatic gastric or gastro-oesophageal junction adenocarcinoma in England each year.		
Process (MTA/STA/HST)	STA		

Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of ramucirumab within its **marketing authorisation** for advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy
Costing implications of remit change	The drug is intended for use as a second line treatment for gastric cancer and gastro-oesophageal junction adenocarcinoma that is locally advanced or metastatic and following disease progression with prior chemotherapy. The estimated number of people who receive first line treatment with chemotherapy for advanced gastric cancer or gastro-oesophageal junction adenocarcinoma is around 1,650 each year. The proportion of these people that may require second line treatment and be eligible for ramicirumab is not known. There is currently no standard second line treatment, although expert opinion suggests a wide range of options including docetaxel are currently being used for this population group. Administration of ramicirumab is by intravenous infusion. The cost of ramicirumab is not known. For this topic to be high cost, additional costs per patient (assuming 100% uptake) would need to be around £9,100 per year.
Timeliness statement	***CONFIDENTIAL INFORMATION REMOVED***