ITEM 5

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 33 draft remits and draft scopes and summary of comments and discussions at scoping workshops

5.1	Dexamethasone intravitreal implant for treating diabetic macular oedema
5.2	Naloxegol for treating opioid-induced constipation
5.3	Vinflunine for previously treated advanced breast cancer
5.4	Ponatinib for treating chronic myeloid leukaemia
5.5	Adalimumab and infliximab for treating moderately active Crohn's disease
5.6	Vedolizumab for treating moderate to severe active Crohn´s disease after prior therapy
5.7	Enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy
5.8	Faldaprevir in combination with peginterferon alfa and ribavirin for treating genotype 1 chronic hepatitis C
5.9	Secukinumab for treating moderate to severe plaque psoriasis

Provisional Title	**Dexamethasone intravitreal implant for treating diabetic macular oedema**		
Topic Selection ID Number	6249	**Wave / Round**	R32
TA ID Number	653		
Manufacturer	Allergan		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of dexamethasone intravitreal implant within its licensed indication for treating diabetic macular oedema.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of dexamethasone intravitreal implant for treating diabetic macular oedema is appropriate. The proposed remit is appropriate. The outcomes should be amended to also include other clinically important outcomes such as change in visual acuity, central foveal subfield thickness and need for cataract surgery. The outcome 'adverse effects of treatment' should specify "including cataract formation and glaucoma". The subgroups for consideration should be changed to include ischaemic or non-ischaemic maculopathy and duration of diabetic macular oedema, and subgroups relating to previous treatment history should include people who have received no prior treatment, and those who have received and/or whose disease is refractory to laser photocoagulation, ranibizumab or bevacizumab.		
Population size	7% of people with diabetes have diabetic macular oedema, of whom 39% have clinically significant disease (i.e. require treatment). This equates to approximately 71,000 people.		
Process (MTA/STA)	STA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	Costing comments updated due to uncertainty around eligible population: The number of people in England with diabetes and visual impairment due to diabetic macular oedema is estimated at around 62,000 (TA 301: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy). It is not known how many of this population would be eligible for treatment with the new technology.		

	For the technology to be classed as high cost, assuming a treatment cost of around £6,100 p/a per patient, around an additional 2,500 people would have to use the technology (excluding savings from other treatments ceased).
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	**Naloxegol for treating opioid-induced constipation**		
Topic Selection ID Number	5668	**Wave / Round**	R34
TA ID Number	674		
Manufacturer	AstraZeneca UK		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of naloxegol within its licensed indication for treating opioid-induced constipation.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of naloxegol for treating opioid-induced constipation is appropriate. The proposed remit is appropriate. Consultees considered that manual evacuation should be removed as a comparator as this treatment would only be considered in people with very severe constipation as a last option and it was noted by the clinical experts that it is not established clinical practice in the UK. Clinical experts confirmed that peripheral mu-opioid antagonists such as methylnaltrexone and naloxone-oxycodone are used for opioid-induced constipation in clinical practice (off label) for patients who have had an inadequate response to oral laxatives. They considered that both methylnaltrexone and naloxone-oxycodone are appropriate comparators for naloxegol (after prior oral laxative use) and should be included in the scope. It should be noted that the comparators in the scope following the proposed updates, are now consistent with a similar topic which is currently being appraised – lubiprostrone for opioid-induced constipation. The outcomes in the draft scope are appropriate but it was agreed at the scoping workshop that response rate, effects on analgesia and upper gastrointestinal symptoms including nausea are other clinically relevant outcomes for naloxegol and should be included in the scope. Consultees raised a concern about the need for defining the treatment pathway for the management of constipation in the UK. It was noted that there are several therapies available but there is no clear guidance on appropriate treatment sequences in the care pathway. The attendees also noted that constipation represents an important condition that affects many people in the UK, and that it involves a substantial amount of healthcare resources. Therefore, it was noted that there is a need for conducting a clinical guideline in the management of constipation.		
Population size	Opioid-induced constipation is considered to be a side effect that will affect nearly all patients taking strong opioid treatment and that will persist unless treated. The precise population size is unknown, but expected to be large.		

Process (MTA/STA)	STA
Proposed changes to remit (in bold)	None
Costing implications of remit change	No changes proposed. The population includes people receiving palliative care for cancers (28,000), but the non-cancer population cannot be quantified at this time. The unit cost is also unknown. Where people switch to naloxegol from comparable treatments (such as methylnaltrexone and naloxone-oxycodone) there will be offsetting savings.
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	**Vinflunine for previously treated advanced breast cancer**		
Topic Selection ID Number	6156	**Wave / Round**	R30
TA ID Number	**635**		
Manufacturer	Pierre-Fabre UK		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of vinflunine within its licensed indication for treating advanced breast cancer in people previously treated with an anthracycline and a taxane.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of vinflunine for previously treated advanced breast cancer is not appropriate given the lack of stakeholder interest and engagement during the scoping process, the small patient population likely to be treated in clinical practice and the view that an appraisal is unlikely to add value to the NHS. Consultees were unable to approximate the size of the clinical population in England who would be treated with vinflunine monotherapy (in line with the proposed indication), however because of its anticipated position late in the treatment pathway, it is assumed that the population will be small. Consultees discussed the proposed position in the chemotherapy treatment pathway for vinflunine combination therapy. The manufacturer noted that vinflunine in combination with capecitabine may be a second-line (or third-line) chemotherapy option because patients may take an anthracycline and taxane in combination at first-line (particularly those who are younger and fitter with a higher tumour burden). The manufacturer approximated that 46% of patients receiving chemotherapy in England for advanced breast cancer receive combination therapy. However, other consultees considered that this estimate was relatively high and noted that the Royal College of Physicians stated in their written consultation response that there is little clinical interest in the combination of vinflunine with capecitabine. Consultees were also aware of the American Society of Clinical Oncology 'Five things Physicians and Patients Should Question (2013)' guideline that states "combination chemotherapy should not be used instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumour-related symptoms". The manufacturer noted that it was aware of these guidelines but felt the recommendations were premature because a number of clinical trials were currently investigating combination chemotherapy in advanced breast cancer. ***Confidential information removed***Consultees acknowledged that the proposed licence population may be broader than the clinical population suitable for vinflunine combination therapy.		

Population size	The manufacturer has estimated that the population size for the proposed combination therapy indication is ***Confidential information removed***. The size of the population for the monotherapy indication is expected to be small.
Process (MTA/STA)	N/A – A referral is not sought
Proposed changes to remit (in bold)	N/A – A referral is not sought
Costing implications of remit change	Treatment with 8 cycles of vinflunine monotherapy incurs drug costs of approximately £18,500, and administration costs of around £800. The average number of cycles administered is, in practice, likely to be lower. Around 6,000 people with advanced breast cancer have been treated with a taxane, but the proportion who have been treated with an anthracycline is unknown. However, it is anticipated that the eligible population will be small. As the cohort of people within England to be treated with the technology is anticipated to be small, this technology is expected to be low cost. Since vinflunine is an alternative to comparators such as gemcitabine or doxorubicin, there are also likely to be offsetting savings.
Timeliness statement	N/A – A referral is not sought

Provisional Title	**Ponatinib for treating chronic myeloid leukaemia**		
Topic Selection ID Number	6446	**Wave / Round**	R49
TA ID Number	671		
Manufacturer	Ariad Pharma UK		
Licensing information	UK marketing authorisation was granted in July 2013 "in adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation". The product was launched in the UK for this indication in August 2013.		
Draft remit	To appraise the clinical and cost effectiveness of ponatinib within its licensed indication for treating chronic myeloid leukaemia.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ponatinib for treating chronic myeloid leukaemia is not appropriate, noting that the population size is very small.A review proposal of existing NICE guidance in CML (TA241) will be considered in September 2014. At that time, the NICE team will discuss whether ponatinib should be included in the review. Clinical specialists at the scoping workshop explained that in the UK imatinib and nilotinib are routinely used as first-line treatments for chronic myeloid leukaemia. For people whose disease is resistant to or who are intolerant to first-line imatinib, nilotinib would normally be used second line. However, if a person received nilotinib first line, imatinib would not be considered as a second-line treatment unless the person was intolerant to, but not resistant to, nilotinib. In the third-line setting, another tyrosine kinase inhibitor would be prescribed if possible in preference to hydroxycarbamide.. Dasatinib and bosutinib, which are not recommended by NICE, are currently used in clinical practice as third- and fourth-line treatments via funding through the Cancer Drugs Fund if the following criteria are met: • Dasatinib: refractory or 'significant intolerance' to imatinib, and 'significant intolerance' to nilotinib (that is, third line). • Bosutinib: refractory to dasatinib or nilotinib, or 'significant intolerance' to dasatinib and nilotinib (that is, third or fourth line). Based on UK clinical practice described by clinical specialists at the Scoping Workshop and the funding criteria of the Cancer Drugs Fund, nilotinib and dasatinib are likely to be used at different stages in the treatment pathway for chronic myeloid leukaemia (nilotinib second line and dasatinib third line). This means that ponatinib, which is licensed after dasatinib or nilotinib, could be used either third or fourth line, so the subpopulations specified in the marketing authorisation for		

	ponatinib (resistance to dasatinib or nilotinib, and intolerance to dasatinib or nilotinib) may not have common comparators. Attendees agreed that people try nilotinib in the second-line setting and move to dasatinib if intolerant or to bosutinib if their disease is resistant, and that people who get dasatinib move to bosutinib when there is resistance or intolerance. Dasatinib was therefore considered a relevant comparator for people with chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia: • who are intolerant to nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate, and bosutinib has been added as a comparator for people: • whose disease is resistant to nilotinib • whose disease is resistant to dasatinib (if they have received it because of intolerance to nilotinib) whose disease is resistant to nilotinib (or dasatinib if they have received it because of intolerance to nilotinib), or who are intolerant to both nilotinib and dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate For people with the T315I mutation, the clinical specialist indicated that no tyrosine kinase inhibitors other than ponatinib are clinically effective, so stem cell transplantation and best supportive care (which includes hydroxycarbamide) would be the only appropriate comparators for this group.
Population size	The manufacturer estimates that 84 patients would be eligible for ponatinib in England each year in line with the marketing authorisation.
Process (MTA/STA)	N/A – A referral is not sought
Proposed changes to remit (in bold)	N/A – A referral is not sought
Costing implications of remit change	Ponatinib is administered orally at 45mg per day. A pack of 30 45mg tablets has a list price of £5,050, giving an annual drug cost of around £61,000. With an estimated population of 84, this gives a total drug cost for England of around £5.2 million assuming the list price was unchanged. Ponatinib is for those who are intolerant or resistant to the alternative drugs. Offsetting costs would include a decrease in demand for best supportive care options due to decreased symptoms, which cannot be quantified.
Timeliness statement	N/A – A referral is not sought

Provisional Title	**Adalimumab and infliximab for treating moderately active Crohn's disease**		
Topic Selection ID Number	6655	**Wave / Round**	R65
TA ID Number	692		
Manufacturer	AbbVie (adalimumab) Merck Sharp & Dohme (infliximab) Manufacturers of biosimilars may be subsequently added		
Licensing information	Adalimumab has a UK marketing authorisation for treating "moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies". Infliximab has a UK marketing authorisation for the "treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies". It is also indicated for the treatment of "fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy)".		
Draft remit	To appraise the clinical and cost effectiveness of adalimumab and infliximab within their licensed indications for treating moderately active Crohn's disease.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of adalimumab and infliximab for treating moderately active Crohn's disease is not appropriate as it is not likely to add value to the NHS. The scoping workshop attendees discussed how the population in the scope should be defined, and agreed that 'moderate' should be clinically defined, and that this should not overlap with the definition of severe disease in TA187. For the purposes of the guidance, TA187 defined severe Crohn's disease as very poor general health and one or more symptoms. The clinical specialists at the scoping workshop stated that this clinical definition would be likely to encompass some of the patients with moderate as well as severe disease, and that this did not provide a clear distinction between the two severities. TA187 further notes that this clinical definition 'normally, but not exclusively, corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more, or a Harvey-Bradshaw score of 8 to 9 or above'. The clinical specialists noted that some patients, with what some might consider moderate active Crohn's disease are offered treatment with TNF-α antagonists, because the recommendations in TA187 leave scope for clinical judgement , and that this affects how the treatments are being prescribed in clinical practice. The clinical specialists stated that, as a result of the TA187 guidance, the Harvey-Bradshaw score was now routinely used in clinical practice in England. They also stated that CDAI scoring was not frequently used		

	because it was difficult to administer. The scoping workshop attendees proposed that the population should be defined in the scope as "Adults with moderately active Crohn's disease (Harvey-Bradshaw score of 5–7) who are intolerant of, or whose condition has not responded adequately to conventional treatment." The scoping workshop attendees discussed the completeness of the list of conventional treatment strategies. It was accepted that antibiotics were a conventional treatment strategy used to treat moderately active Crohn's disease in routine clinical practice in England, and that they should be added to the list of conventional treatment strategies in the draft scope. Consultation responses suggested that patients with moderately active Crohn's disease who have poor prognostic factors may experience a greater treatment benefit than the overall population with moderately active disease. Therefore it was agreed that this population should be considered as a subgroup if the evidence allows. Noting that the trials informing the licence extension of the treatments in the moderate disease setting have already been considered as part of TA187, the scoping workshop attendees were unable to suggest an optimal way to proceed with an appraisal of adalimumab and infliximab for treating moderately severe Crohn's disease. They agreed that if the topic was referred for appraisal that it would be preferable to undertake a very large MTA covering moderate to severe disease and to also include vedolizumab.It was noted that if the MTA was accepted then it should not be commenced until the STA for vedolizumab (see item 5.6) has been completed.
Population size	There are currently at least 80,000 people in England with Crohn's disease. It is unclear what proportion has moderate disease.
Process (MTA/STA)	N/A – A referral is not sought
Proposed changes to remit (in bold)	N/A – A referral is not sought
Costing implications of remit change	It is unclear how many additional patients would be eligible for treatment with these technologies, although it is unlikely that it would be large. Assuming an annual cost of £10,000, around an additional 1,500 people would need to use the technology for it to be classed as high cost.
Timeliness statement	N/A – A referral is not sought

Provisional Title	**Vedolizumab for treating moderate to severe active Crohn´s disease after prior therapy**		
Topic Selection ID Number	6665	**Wave / Round**	R67
TA ID Number	690		
Manufacturer	Takeda UK		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of vedolizumab within its licensed indication for treating moderate to severe active Crohn´s disease in people who are intolerant of, or whose disease has not responded or is resistant to either conventional therapy or a tumour necrosis factor-alpha (TNF-α) antagonist.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of vedolizumab for treating moderate to severe active Crohn´s disease after prior therapy is appropriate. The proposed remit is appropriate. The population in the scope should be changed to 'adults' in line with the anticipated marketing authorsation. The examples of conventional treatments in the scope should be expanded to include antibiotics for people with moderate active Crohn's disease as they are widely used in clinical practice. Consultees also discussed whether biosimilars should be included as comparators in the scope. It was noted that at the time vedolizumab will be referred for appraisal, biosimilars will not be available in the NHS. As biosimilars are not expected to be in established NHS practice at the time of appraisal they cannot be considered established clinical practice and therefore should not be considered as comparators for vedolizumab. If the evidence allows, a subgroup of people whose disease has failed to previous treatment with TNF-α antagonists should be considered. In order to ensure timely guidance, an STA is the most appropriate process to consider this topic..		
Population size	There are currently at least 80,000 people in England with Crohn´s disease.		
Process (MTA/STA)	STA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	Although the eligible population is estimated to be around 7,900, this topic will only be classed as high cost if the new technology costs around £2,000 p/a more than current		

	treatments (and also assuming the entire eligible population switch to vedolizumab). Where people switch from existing treatments such as infliximab and adalimumab, there will be no cost impact to the NHS if the new technology costs around the same per year as these treatments.
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	**Enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy**		
Topic Selection ID Number	6385	**Wave / Round**	R44
TA ID Number	683		
Manufacturer	Astellas Pharma		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of enzalutamide within its licensed indication for treating metastatic, hormone-relapsed prostate cancer that has not been 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 enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy is appropriate. The proposed remit is not appropriate and should be changed to reflect the anticipated marketing authorisation: "To appraise the clinical and cost effectiveness of enzalutamide within its licensed indication for treating metastatic, hormone-relapsed prostate cancer <u>for people in whom chemotherapy is not yet clinically indicated</u>." This proposed wording will also align the population in line with that of abiraterone which is already licenced for this indication. Attendees at the workshop noted that although the draft remit was not entirely wrong, it did not reflect the anticipated wording of the licence. They stated that the phrase "that has not been previously treated with chemotherapy" was slightly misleading as it seemed to suggest that enzalutamide would be used as an alternative to chemotherapy. The attendees stated that in clinical practice, people do not receive chemotherapy immediately after disease progression following treatment with hormone therapy, even if they are medically fit to receive it. They stated that chemotherapy was usually delayed for as long as necessary because of the unpleasant side effects and in the meantime, people received best supportive care which includes corticosteroids such as dexamethasone or prednisolone. They indicated that the expectation was for enzalutamide to be used as an alternative to best supportive care based on the pivotal clinical trial in order to prolong the time before initiating chemotherapy. The workshop attendees referred to the marketing authorisation for abiraterone which is "for people in whom chemotherapy is not yet clinically indicated", and noted that the marketing authorisation for enzalutamide would likely be similar to that. . The population in the scope was considered to be too broad as it does not reflect the specific population for whom enzalutamide will likely be licensed. Based on the suggested change to the remit, it was agreed that the population should be updated to "Adults with asymptomatic or mildly symptomatic		

	metastatic hormone-relapsed prostate cancer in whom chemotherapy is not yet clinically indicated". Attendees at the workshop did not consider docetaxel to be an appropriate comparator for enzalutamide. They indicated that enzalutamide was compared with placebo rather than docetaxel in the trial because it was intended to be used in people who would eventually receive chemotherapy. It was noted that patients in the trial eventually received chemotherapy on disease progression. Based on the current care pathway, the workshop attendees considered that the appropriate comparators for enzalutamide were best supportive care (including dexamethasone or prednisolone) and abiraterone. However, it was noted that although patients on these treatments would eventually receive chemotherapy, the time to initiation of chemotherapy was expected to be considerably shorter in people who received best supportive care than in people who received abiraterone or enzalutamide. Therefore the attendees considered it appropriate to compare the pathways rather than the individual treatments alone, that is, to include subsequent chemotherapy to each treatment being compared. Therefore, the comparators should be amended to: • Best supportive care and subsequent chemotherapy • Abiraterone and subsequent chemotherapy The outcome progression-free survival should be defined according to trial endpoints as "Progression-free survival (radiographic and prostate specific antigen response)". Time to initiation of chemotherapy should also be included in the scope as a clinically important outcome.
Population size	Consultees estimated that there are approximately 4800 patients in the UK who would be eligible to receive enzalutamide for this indication.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of enzalutamide within its licensed indication for treating metastatic, hormone-relapsed prostate cancer **for people in whom chemotherapy is not yet clinically indicated** ~~that has not been previously treated with chemotherapy~~.
Costing implications of remit change	The change in remit does not affect the position in the treatment pathway for the new technology. However, a unit cost is now available. The costing comments have therefore been updated to: The estimated eligible population for this technology is between 4200 and 4800 (mid-point 4500). The cost for a 4-week supply of enzalutamide is £2734.67. Although the treatment period is unclear, assuming a treatment period of 9 weeks, the cost per person is around £6150. Given an eligible population of around 4500 it is therefore likely that this technology will be high 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	**Faldaprevir in combination with peginterferon alfa and ribavirin for treating genotype 1 chronic hepatitis C**		
Topic Selection ID Number	6148	**Wave / Round**	R27
TA ID Number	670		
Manufacturer	Boehringer Ingelheim		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of faldaprevir within its licensed indication for treating genotype 1 chronic hepatitis C.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of faldaprevir is appropriate. The proposed remit is appropriate. Consultees discussed the wording for the population 'adults with genotype 1 chronic hepatitis C in whom previous treatment with peginterferon alfa and ribavirin has been ineffective' and considered that the term 'ineffective' suggests that the treatment has never shown any effect, which was misleading. It was agreed that the critical outcome of treatment was sustained virological response, and therefore the wording of the population should be amended to 'adults with chronic hepatitis C in whom previous treatment with peginterferon alfa and ribavirin has not resulted in a sustained virological response.' During consultation, consultees acknowledged that the duration of treatment with faldaprevir may be adapted depending on a patient's rapid virological response to treatment, and that patients who do not show a rapid virological response at specific time points may discontinue treatment. Attendees agreed that rapid virological response was an important outcome to capture in the scope. Consultees also considered that the development of resistance to faldaprevir should be considered as an outcome as it was likely to affect treatment discontinuation rates. Attendees at the scoping workshop recognised that there are other products in the NICE work programme relating to chronic hepatitis C and that it would be valuable to conduct an MTA that compared them all. It was agreed, however, that an STA was appropriate in this instance so that any guidance on the use of faldaprevir would be timely.		
Population size	There are approximately 215,000 people chronically infected with hepatitis C in the UK; however only a small proportion of patients are treated (approximately 17,000 people).		
Process (MTA/STA)	STA		

Proposed changes to remit (in bold)	None
Costing implications of remit change	None
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	**Secukinumab for treating moderate to severe plaque psoriasis**		
Topic Selection ID Number	6135	**Wave / Round**	R24
TA ID Number	718		
Manufacturer	Novartis		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of secukinumab within its licensed indication for moderate to severe plaque psoriasis in people for whom other systemic therapies have been inadequately effective, not tolerated or contraindicated.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of secukinumab for treating moderate to severe plaque psoriasis is appropriate. The proposed remit is appropriate. It should be noted that the anticipated marketing authorisation for secukinumab is likely to be broad and allow use before, during or after systemic therapy. However the clinical experts and manufacturer acknowledged during consultation that secukinumab is most likely to be used after systemic therapies. The manufacturer confirmed that 15-20% of patients in the clinical trials had previously received biologics. Consultees therefore suggested that prior biologic use should be added as a subgroup for consideration if evidence allows. Consultees noted that biosimilars have not yet been launched in the UK (expected 2015) for plaque psoriasis and are therefore they are not expected to established NHS practice at the time of appraisal and should be removed as potential comparators from the scope. Consultees agreed that best supportive care should be added as a comparator, for those for whom biological therapies are not tolerated or contraindicated.		
Population size	An estimated 1.1% of people are eligible for the psoriasis drugs which NICE currently recommends (for severe psoriasis), which equates to around 7,100 people, and of these around 50% would receive biological therapy (based on clinical opinion).		
Process (MTA/STA)	STA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	No change due to change in remit. However, costing comments have been changed slightly to reflect the slightly lower anticipated eligible population: Secukinumab is intended for the treatment of moderate to severe plaque psoriasis as an alternative to existing biologic therapies. It is estimated that around 3,600 people with severe psoriasis may be eligible for treatment with the new technology. The total eligible population may be higher than this since it		

	includes moderate psoriasis. The cost of secukinumab is not yet known. The annual cost of comparable drugs range from £8,000 to £10,000. For this technology to be high cost, the actual cost would need to be around £4,200 more than current alternatives assuming everybody switched. As the actual cost and uptake rate cannot be estimated with any certainty at this point, the cost impact cannot be estimated. However since this technology represents a further option for the treatment of plaque psoriasis it 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.