NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

St George's Healthcare NHS Trust Compliance indicator key for medicine-related NICE Technology Appraisals

A. Guidance has been approved by the Drugs and Therapeutics Committee as recommended within the NICE technology appraisal
B. Guidance has been terminated or not recommended
C. Guidance is not relevant to the Trust as the treatment pathway is not commissioned

Red: St George's Healthcare formulary diverges from the NICE recommendations

Green: Approved on National Cancer Drug Fund (CDF) list for specific indications (provided patient fulfils specific criteria)

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
330	Sofosbuvir for treating chronic hepatitis C	Feb 2015	Sofosbuvir is recommended as an option for treating chronic hepatitis C in adults as recommened in the full NICE TA guidance	Formulary	A
332	Sipuleucel-T for treating asymptomatic or minimally symptomatic metastatic hormone-relapsed prostate cancer	Feb 2015	Sipuleucel-T is not recommended within its marketing authorisation for treating adults who have asymptomatic or minimally symptomatic metastatic non-visceral hormone-relapsed prostate cancer for which chemotherapy is not yet clinically indicated	Non-formulary	B
331	Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C	Feb 2015	Simeprevir, in combination with peginterferon alfa and ribavirin, is recommended within its marketing authorisation as an option for treating genotype 1 and 4 chronic hepatitis C in adults.	Formulary	A
334	Regorafenib for metastatic colorectal cancer after treatment for metastatic disease	Feb 2015	Appraisal Terminated	Non-formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
329	Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)	Feb 2015	1) Infliximab, adalimumab and golimumab are recommended, within their marketing authorisations, as options for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme. 2) The choice of treatment between infliximab, adalimumab or golimumab should be made on an individual basis after discussion between the responsible clinician and the patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). 3) Infliximab is recommended, within its marketing authorisation, as an option for treating severely active ulcerative colitis in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. 4) Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate:	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

			They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.		

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
333	Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment	Feb 2015	1) Axitinib is recommended as an option for treating adults with advanced renal cell carcinoma after failure of treatment with a first-line tyrosine kinase inhibitor or a cytokine, only if the company provides axitinib with the discount agreed in the patient access scheme. 2) At the time of publication (February 2015), axitinib has a UK marketing authorisation only for use after failure with first-line sunitinib or a cytokine. If it is considered for use after any other first-line treatments, the prescriber should obtain and document informed consent and follow the relevant guidance published by the General Medical Council. 3) Because the remit referred to NICE by the Department of Health for this technology appraisal only includes adults who have been previously treated with sunitinib, the use of axitinib after treatment with other tyrosine kinase inhibitors is not subject to statutory funding.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
335	Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome	Mar 2015	1) Rivaroxaban is recommended as an option within its marketing authorisation, in combination with aspirin plus clopidogrel or aspirin alone, for preventing atherothrombotic events in people who have had an acute coronary syndrome with elevated cardiac biomarkers. 2) Clinicians should carefully assess the person's risk of bleeding before treatment with rivaroxaban is started. The decision to start treatment should be made after an informed discussion between the clinician and the patient about the benefits and risks of rivaroxaban in combination with aspirin plus clopidogrel or with aspirin alone, compared with aspirin plus clopidogrel or aspirin alone. 3) A decision on continuation of treatment should be taken no later than 12 months after starting treatment. Clinicians should regularly reassess the relative benefits and risks of continuing treatment with rivaroxaban and discuss them with the patient.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
336	Empagliflozin in combination therapy for treating type 2 diabetes	Mar 2015	1) Empagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if: • a sulfonylurea is contraindicated or not tolerated, or • the person is at significant risk of hypoglycaemia or its consequences. 2) Empagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with: • metformin and a sulfonylurea or • metformin and a thiazolidinedione. 3) Empagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes. People currently receiving treatment initiated within the NHS with empagliflozin that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Formulary	A
337	Rifaximin for preventing episodes of overt hepatic encephalopathy	Mar 2015	Rifaximin is recommended, within its marketing authorisation, as an option for reducing the recurrence of episodes of overt hepatic encephalopathy in people aged 18 years or older.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
338	Pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib	Mar 2015	Pomalidomide, in combination with dexamethasone, is not recommended within its marketing authorisation for treating relapsed and refractory multiple myeloma in adults who have had at least 2 previous treatments, including lenalidomide and bortezomib, and whose disease has progressed on the last therapy. People whose treatment with pomalidomide was started within the NHS before this guidance was published should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Non-formulary	A
339	Omalizumab for previously treated chronic spontaneous urticaria	June 2015	Omalizumab (Xolair) is recommended as a possible treatment for people aged 12 years and over with severe chronic spontaneous urticaria if: • a doctor has objectively diagnosed the condition as severe • the condition has not improved with standard treatment with H1-antihistamines or leukotriene receptor antagonists • the drug is stopped at or before the fourth dose if the condition has not responded • the drug is stopped at the end of a course of treatment (6 doses) if the condition has responded, and is only restarted if the condition comes back • the drug is given by a secondary care specialist in dermatology, immunology or allergy.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
340	Ustekinumab for treating active psoriatic arthritis (rapid review of technology appraisal guidance 313)	June 2015	Ustekinumab (Stelara) is recommended as a possible treatment, alone or with a drug called methotrexate, for adults with active psoriatic arthritis when treatment with non-biological disease-modifying antirheumatic drugs (or DMARDS) has not worked well enough if: • treatment with tumour necrosis factor (TNF) alpha inhibitors is not suitable for them, or • the person has had a TNF alpha inhibitor before. Treatment with ustekinumab should be stopped after 24 weeks if it is not working well enough	Formulary	A
341	Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism	June 2015	Apixaban (Eliquis) is recommended as an option for treating and preventing recurrent deep vein thrombosis or pulmonary embolism.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
342	Vedolizumab for treating moderately to severely active ulcerative colitis	June 2015	Vedolizumab (Entyvio) is recommended as a possible treatment for adults with moderate to severe ulcerative colitis. People should be able to have the treatment until it stops working or surgery is needed. Their condition should be assessed 12 months after they started taking vedolizumab. If they still have symptoms but it is clear that the treatment is helping, they can continue to have it. If they no longer have symptoms, treatment could be stopped, and later restarted if symptoms return. People who continue to take vedolizumab should be assessed at least every 12 months to see whether the treatment is working well enough for them to carry on taking it.	Formulary	A
343	Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia	June 2015	Obinutuzumab (Gazyvaro), given with a drug called chlorambucil, is recommended as a possible treatment for adults with untreated chronic lymphocytic leukaemia only if: • they have other conditions that make full-dose fludarabine unsuitable for them and • bendamustine is not suitable for them.	Formulary	A
344	Ofatumumab in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia	June 2015	Ofatumumab (Arzerra) given with a drug called chlorambucil is recommended as a possible treatment for people with untreated chronic lymphocytic leukaemia if treatments containing fludarabine or bendamustine are not suitable	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
345	Naloxegol for treating opioid-induced constipation	July 2015	Naloxegol (Moventig) is recommended as a possible treatment for people with opioid induced constipation that has had an inadequate response to laxatives.	Formulary	A
346	Aflibercept for treating diabetic macular oedema	July 2015	Aflibercept (Eylea) injections are recommended as a possible treatment for some people with sight problems caused by diabetic macular oedema, as explained below.	Patient treatment pathway not provided at St George's (commissioning decision)	C
347	Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer	July 2015	Nintedanib (Vargatef), given with a drug called docetaxel, is recommended. It is a possible treatment for people with a certain type (adenocarcinoma) of locally advanced, metastatic or locally recurrent non-small-cell lung cancer that has got worse after previous chemotherapy.	Formulary	A
348	Everolimus for preventing organ rejection in liver transplantation	July 2015	Everolimus (Certican) is not recommended for preventing organ rejection in people having a liver transplant.	Patient treatment pathway not provided at St George's (commissioning decision)	C
349	Dexamethasone intravitreal implant for treating diabetic macular oedema	July 2015	Dexamethasone intravitreal implant (Ozurdex) is recommended as a possible treatment for people with sight problems caused by diabetic macular oedema if: • there is an artificial lens in the eye to be treated, and • their diabetic macular oedema has not improved with non-corticosteroid treatment, or such treatment is not suitable for them	Patient treatment pathway not provided at St George's (commissioning decision)	C

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
350	Secukinumab for treating moderate to severe plaque psoriasis	July 2015	Secukinumab (Cosentyx) is recommended as a possible treatment for people with plaque psoriasis if: • standard assessments show that their psoriasis is severe and is affecting their quality of life, and • their psoriasis has not improved with other treatments including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or they have had side effects with these treatments in the past or there is a reason why they cannot have them. Treatment with secukinumab should be stopped after 12 weeks if the psoriasis does not improve enough according to standard measures	Formulary	A
351	Cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti-platelet therapy	July 2015	Appraisal Terminated	Non-formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
352	Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy	Aug 2015	Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease only if: • a tumour necrosis factor-alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment) or • a tumour necrosis factor-alpha inhibitor cannot be tolerated or is contraindicated. Vedolizumab is recommended only if the company provides it with the discount agreed in the patient access scheme. Vedolizumab should be given as a planned course of treatment until it stops working or surgery is needed, or until 12 months after the start of treatment, whichever is shorter. At 12 months, people should be reassessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to decide whether continued treatment is justified. People whose treatment with vedolizumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
353	Bevacizumab for treating relapsed, platinum‐resistant epithelial ovarian, fallopian tube or primary peritoneal cancer	Aug 2015	Appraisal Terminated	Non-formulary	B
354	Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism	Aug 2015	Edoxaban (Lixiana) is recommended as an option for treating and preventing recurrent deep vein thrombosis or pulmonary embolism.	Formulary	A
355	Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation	Sept 2015	Edoxaban (Lixiana) is recommended as an option for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation who have one or more risk factors, such as: • heart failure, high blood pressure or diabetes • had a stroke or transient ischaemic attack before • aged 75 years or older.	Formulary	A
356	Ruxolitinib for treating polycythaemia vera (terminated appraisal)	Sept 2015	Appraisal Terminated	Non-formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
357	Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab	Oct 2015	Pembrolizumab (Keytruda) is recommended. This drug is a possible treatment for adults with melanoma that: • can't be completely removed by surgery or has spread to other parts of the body • has been treated with ipilimumab (melanoma that is BRAF V600 mutation-positive must also have had treatment with vemurafenib, dabrafenib, or trametinib).	Formulary	A
358	Tolvaptan for treating autosomal dominant polycystic kidney disease	Oct 2015	Tolvaptan (Jinarc) is recommended as a possible treatment for people with autosomal dominant polycystic kidney disease if: • they have chronic kidney disease stage 2 or 3 at the start of treatment and • there is evidence of rapidly progressing disease.	Formulary	A
359	Idelalisib for treating chronic lymphocytic leukaemia	Oct 2015	Idelalisib (Zydelig), given with a drug called rituximab, is recommended as a possible treatment for adults with: • untreated chronic lymphocytic leukaemia, only if they have certain genetic characteristics • chronic lymphocytic leukaemia, only if it has been treated but has come back within 2 years.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
360	Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer	Oct 2015	Nab-paclitaxel (Abraxane) with gemcitabine (Gemzar) is not recommended for adults with metastatic adenocarcinoma of the pancreas that has not been treated before	Non-Formulary for this indication	B
361	Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C	Oct 2015	Appraisal terminated	Individual drugs are on the formulary for specific indications; the two drugs will not be used together until evidence has been published by NICE	A
362	Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer	Oct 2015	Appraisal Terminated	Non-formulary for this indication	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
363	Ledipasvir–sofosbuvir for treating chronic hepatitis C	Nov 2015	Ledipasvir-sofosbuvir (Harvoni) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis C If the hepatitis C has not been treat before: • Type 1 without cirrhosis – 8 weeks treatment with Ledipasvir-sofosbuvir is recommended • Type 1 or 4 with cirrhosis – 12 weeks treatment with Ledipasvir-sofosbuvir is recommended If the hepatitis C has been treated before, but has not responded well enough: • Type 1 or 4 without cirrhosis – 12 weeks treatment with Ledipasvir-sofosbuvir is recommended • Type 1 or 4 with cirrhosis – 12 weeks treatment, only if the person has a low risk of the disease getting worse	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
364	Daclatasvir for treating chronic hepatitis C	Nov 2015	Daclatasvir (Daklinza) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis C, depending on their level of fibrosis. It is taken with sofosbuvir or peginteron alfa, and sometimes with a drug called ribavirin. If the hepatitis C has not been treated before: • Type 1 without cirrhosis – 12 weeks treatment is recommended of declatasvir with sofosbuvir for people with significant fibrosis • Type 4 – 24 weeks treatment is recommended of daclatasvir plus peginterferon alfa and ribavirin only for people with significant fibrosis or cirrhosis If the hepatitis C has been treated before: • Type 1 or 4 without cirrhosis – 12 weeks treatment is recommended of daclatasvir plus sofosbuvir only for people with significant fibrosis • Type 4 – 24 weeks treatment is recommended of daclatasvir plus peginterferon alfa and ribavirin only for people with significant fibrosis or cirrhosis If the patient cannot have interferon: • Type 1,3 or 4 without cirrhosis – 12 weeks treatment is recommended of daclatasvir plus sofosbuvir only for people with significant fibrosis • Type 1 or 4 with cirrhosis – 24 weeks treatment is recommended of daclatasvir plus sofosbuvir, with or without ribavirin • Type 3 with cirrhosis – 24 weeks treatment is recommended of daclatasvir plus sofosbuvir and ribavirin	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
365	Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C	Nov 2015	Ombitasvir–paritaprevir–ritonavir (Viekirax) with or without dasabuvir (Exviera) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis C. It is sometimes taken with ribavirin. Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for adults with chronic hepatitis C: • Type 1a without cirrhosis – 12 weeks treatment of Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin • Type 1a with cirrhosis – 24 weeks treatment of Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin • Type 1b withour cirrhosis – 12 weeks treatment of Ombitasvir–paritaprevir–ritonavir with dasabuvir • Type 1b with cirrhosis – 12 weeks treatment of Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin • Type 4 without cirrhosis – 12 weeks treatment of Ombitasvir–paritaprevir–ritonavir with ribavirin • Type 4 with cirrhosis – 24 weeks treatment of Ombitasvir–paritaprevir–ritonavir with ribavirin	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
366	Pembrolizumab for advanced melanoma not previously treated with ipilimumab	Nov 2015	Pembrolizumab (Keytruda) is recommended. This drug is a possible treatment for adults with melanoma that: • can't be completely removed by surgery or has spread to other parts of the body • has not been treated with ipilimumab before.	Formulary	A
367	Vortioxetine for treating major depressive episodes	Nov 2015	Vortioxetine (Brintellix) is recommended as a possible treatment for adults having a first or recurrent major depressive episode, if the current episode has not responded to 2 antidepressants.	Formulary	A
368	Apremilast for treating moderate to severe plaque psoriasis	Nov 2015	Apremilast (Otezla) is **not recommended** for treating moderate to severe chronic plaque psoriasis in adults whose psoriasis has not improved with other treatments, or they have had side effects with these treatments in the past or there is a reason why they cannot have them.	Non-formulary	B
369	Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears	Dec 2015	Ciclosporin (Ikervis) is recommended as a possible treatment for people with dry eye disease that has not improved despite treatment with artificial tears.	Patient treatment pathway not provided at St George's (commissioning decision)	C
370	Bortezomib for previously untreated mantle cell lymphoma	Dec 2015	Bortezomib (Velcade) is recommended as a possible treatment for adults with mantle cell lymphoma that has not been treated before, if haematopoietic stem cell transplantation is not suitable for them.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
371	Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane	Dec 2015	Trastuzumab emtansine (Kadcyla) is **not recommended**. This drug is for adults with advanced HER2-positive breast cancer that has been treated before with trastuzumab and a taxane (paclitaxel or docetaxel).	Non-Formulary	B
372	Apremilast for treating active psoriatic arthritis	Dec 2015	Superseded by NICE TA 433 – see below	See NICE TA 433	
373	Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis	Dec 2015	Abatacept (Orencia), adalimumab (Humira), etanercept (Enbrel) and tocilizumab (RoActemra) are recommended as possible treatments for people with polyarticular juvenile idiopathic arthritis. Adalimumab and etanercept are recommended as possible treatments for people with enthesitis-related juvenile idiopathic arthritis. Etanercept is recommended as a possible treatment for people with psoriatic juvenile idiopathic arthritis.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
374	Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy	Dec 2015	Erlotinib (Tarceva) is recommended as a possible treatment for people with locally advanced or metastatic non-small-cell lung cancer that has already been treated with non-targeted chemotherapy because of delayed confirmation of epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation status, if: •their cancer tests positive for the EGFR-TK mutation or •it is not known if the cancer is EGFR-TK mutation-positive because of problems with the test, and - the cancer is very likely to be EGFR-TK mutation-positive - it responds to the first 2 cycles of treatment with erlotinib. Erlotinib is **not recommended** for treating locally advanced or metastatic non-small-cell lung cancer that doesn't test positive for the EGFR-TK mutation. Gefitinib (Iressa) is **not recommended** for treating non-small-cell lung cancer that has progressed after chemotherapy.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
375	Evidence-based recommendations on adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade, Remsima, Inflectra), certolizumab pegol (Cimzia), golimumab (Simponi), tocilizumab (RoActemra) and abatacept (Orencia). These drugs are for people with severe rheumatoid arthritis who have tried conventional DMARDs only but they have not worked.	Jan 2016	This guidance replaces NICE technology appraisal guidance on: •adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis (TA130) •certolizumab pegol for the treatment of rheumatoid arthritis (TA186) •golimumab for the treatment of methotrexate-naive rheumatoid arthritis (TA224) and •abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (TA280). It partially updates golimumab for the treatment of rheumatoid arthritis after the failure of previous disease-modifying anti-rheumatic drugs (TA225) and tocilizumab for the treatment of rheumatoid arthritis (TA247).	Formulary	A
376	Evidence-based recommendations on radium-223 dichloride (Xofigo) for treating hormone-relapsed prostate cancer with bone metastases.	Jan 2016	Radium-223 dichloride is recommended as an option for treating adults with hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases, only if: •they have had treatment with docetaxel, and •the company provides radium-223 dichloride with the discount agreed in the patient access scheme.	Patient treatment pathway not provided at St George's (commissioning decision)	C

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
377	Evidence-based recommendations on enzalutamide (Xtandi) for treating metastatic, hormone-relapsed prostate cancer for people in whom chemotherapy is not yet clinically indicated.	Jan 2016	Enzalutamide is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer: •in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated •and only when the company provides it with the discount agreed in the patient access scheme.	Formulary	A
378	Recommendations on ramucirumab (Cyramza) for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy.	Jan 2016	Ramucirumab alone or with paclitaxel is **not recommended** within its marketing authorisation for advanced gastric cancer or gastro–oesophageal junction adenocarcinoma previously treated with chemotherapy.	Patient treatment pathway not provided at St George's (commissioning decision)	C
379	Evidence-based recommendations on nintedanib (Ofev) for people with idiopathic pulmonary fibrosis.	Jan 2016	Nintedanib is recommended as an option for treating idiopathic pulmonary fibrosis, only if: •the person has a forced vital capacity (FVC) between 50% and 80% of predicted •the company provides nintedanib with the discount agreed in the patient access scheme and •treatment is stopped if disease progresses (a confirmed decline in per cent predicted FVC of 10% or more) in any 12-month period.	Patient treatment pathway not provided at St George's (commissioning decision)	C

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
380	Evidence-based recommendations on panobinostat (Farydak) for treating multiple myeloma after at least 2 previous treatments.	Jan 2016	Panobinostat in combination with bortezomib and dexamethasone is recommended, within its marketing authorisation, as an option for treating multiple myeloma, that is, for 'adult patients with relapsed and/or refractory multiple myeloma who have received at least 2 prior regimens including bortezomib and an immunomodulatory agent' when the company provides panobinostat with the discount agreed in the patient access scheme.	Formulary	A
381	Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy	Jan 2016	Olaparib is recommended within its marketing authorisation as an option for treating adults with relapsed, platinum sensitive ovarian, fallopian tube or peritoneal cancer who have BRCA1 or BRCA2 mutations and whose disease has responded to platinum based chemotherapy only if: •they have had 3 or more courses of platinum based chemotherapy and •the drug cost of olaparib for people who remain on treatment after 15 months will be met by the company.	Formulary	A
382	Eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy (terminated appraisal)	Jan 2016	Appraisal terminated	Non-Formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
383	TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis	Feb 2016	Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non‑steroidal anti‑inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

			Treatment should only be continued if there is clear evidence of response, defined as: •a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and •a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.		

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
384	Nivolumab for treating advanced (unresectable or metastatic) melanoma	Feb 2016	Nivolumab as monotherapy is recommended, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults.	Formulary	A
385	Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia	Feb 2016	This guidance updates and replaces NICE technology appraisal guidance on ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (TA132).	Formulary	A
386	Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis	March 2016	Ruxolitinib is recommended as an option for treating disease-related splenomegaly or symptoms in adults with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, only: •in people with intermediate-2 or high-risk disease, and •if the company provides ruxolitinib with the discount agreed in the patient access scheme.	Formulary	A
387	Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	March 2016	Abiraterone in combination with prednisone or prednisolone is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer: •in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated •only when the company rebates the drug cost of abiraterone from the 11th month until the end of treatment for people who remain on treatment for more than 10 months.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
388	Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction	April 2016	Sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction, only in people: •with New York Heart Association (NYHA) class II to IV symptoms and •with a left ventricular ejection fraction of 35% or less and •who are already taking a stable dose of angiotensin‑converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs). Treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults: management.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
389	Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer	April 2016	Paclitaxel in combination with platinum or as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer. Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer. PLDH in combination with platinum is recommended as an option for treating recurrent ovarian cancer The following are **not recommended** within their marketing authorisations for treating the first recurrence of platinum-sensitive ovarian cancer: •gemcitabine in combination with carboplatin •trabectedin in combination with PLDH •topotecan. Topotecan **is not recommended** within its marketing authorisation for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
390	Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes	May 2016	Canagliflozin, dapagliflozin and empagliflozin as monotherapies are recommended as options for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if: •a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and •a sulfonylurea or pioglitazone is not appropriate.	Formulary	A
391	Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel	May 2016	Cabazitaxel in combination with prednisone or prednisolone is recommended as an option for treating metastatic hormone-relapsed prostate cancer in people whose disease has progressed during or after docetaxel chemotherapy, only if: •the person has an eastern cooperative oncology group (ECOG) performance status of 0 or 1 •the person has had 225 mg/m2 or more of docetaxel •treatment with cabazitaxel is stopped when the disease progresses or after a maximum of 10 cycles (whichever happens first) •NHS trusts purchase cabazitaxel in pre-prepared intravenous-infusion bags, not in vials, and •the company provides cabazitaxel with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
392	Adalimumab for treating moderate to severe hidradenitis suppurativa	June 2016	Adalimumab is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme. Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as: • a reduction of 25% or more in the total abscess and inflammatory nodule count and • no increase in abscesses and draining fistulas.	Formulary	A
393	Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	June 2016	Alirocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: • Low-density lipoprotein concentrations are persistently above specified thresholds despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia: identification and management). • The company provides alirocumab with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
394	Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	June 2016	Evolocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: • The dosage is 140 mg every 2 weeks. • Low-density lipoprotein concentrations are persistently above specified thresholds despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached, or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia). • The company provides evolocumab with the discount agreed in the patient access scheme.	Formulary	A
395	Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer	June 2016	Ceritinib is recommended, within its marketing authorisation, as an option for treating advanced anaplastic lymphoma kinase positive non‑small‑cell lung cancer in adults who have previously had crizotinib. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
396	Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma	June 2016	Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes.	Formulary	A
397	Belimumab for treating active autoantibody-positive systemic lupus erythematosus	June 2016	Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults only if all of the following apply: • There is evidence for serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of greater than or equal to 10 despite standard treatment. • Treatment with belimumab is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more. • The company provides belimumab with the discount agreed in the patient access scheme. • Under the conditions for data collection, monitoring, patient eligibility and consent, ongoing treatment, cost to the NHS, and review by NICE as laid out in the managed access agreement.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
398	Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation	July 2016	Lumacaftor–ivacaftor is **not recommended**, within its marketing authorisation, for treating cystic fibrosis in people 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Non-Formulary	B
399	Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts	July 2016	Azacitidine is **not recommended**, within its marketing authorisation, for treating acute myeloid leukaemia with more than 30% bone marrow blasts in people of 65 years or older who are not eligible for haematopoietic stem cell transplant.	Non-Formulary	B
400	Nivolumab in combination with ipilimumab for treating advanced melanoma	July 2016	Nivolumab in combination with ipilimumab is recommended, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults, only when the company provides ipilimumab with the discount agreed in the patient access scheme.	Formulary	A
401	Bosutinib for previously treated chronic myeloid leukaemia	August 2016	Bosutinib is recommended as an option, within its marketing authorisation, for chronic, accelerated and blast phase Philadelphia chromosome positive chronic myeloid leukaemia in adults, when: • they have previously had 1 or more tyrosine kinase inhibitor and • imatinib, nilotinib and dasatinib are not appropriate and • the company provides bosutinib with the discount agreed in the patient access scheme (as revised in 2016).	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
402	Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin	August 2016	Pemetrexed is recommended as an option for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer in adults when: • their disease has not progressed immediately after 4 cycles of pemetrexed and cisplatin induction therapy • their Eastern Cooperative Oncology Group (ECOG) performance status is 0 or 1 at the start of maintenance treatment and • the company provides the drug according to the terms of the commercial access agreement as agreed with NHS England. When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
403	Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer	August 2016	Ramucirumab, in combination with docetaxel, is **not recommended** within its marketing authorisation for treating locally advanced or metastatic non-small-cell lung cancer in adults whose disease has progressed after platinum-based chemotherapy.	Non-Formulary	B
404	Degarelix for treating advanced hormone-dependent prostate cancer	August 2016	Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016.	Formulary	A
405	Trifluridine–tipiracil for previously treated metastatic colorectal cancer	August 2016	Trifluridine–tipiracil is recommended, within its marketing authorisation, as an option for treating metastatic colorectal cancer, that is: • in adults who have had previous treatment with available therapies including fluoropyrimidine-, oxaliplatin- or irinotecan-based chemotherapies, anti-vascular endothelial growth factor (VEGF) agents and anti-epidermal growth factor receptor (EGFR) agents, or when these therapies are not suitable, and • only when the company provides trifluridine–tipiracil with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
406	Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	September 2016	Crizotinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer in adults. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	Formulary	A
407	Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors	September 2016	Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF‑alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme. Assess the response to secukinumab after 16 weeks of treatment and only continue if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
407	Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors	September 2016	Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme. Assess the response to secukinumab after 16 weeks of treatment and only continue if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
408	Pegaspargase for treating acute lymphoblastic leukaemia	September 2016	Pegaspargase, as part of antineoplastic combination therapy, is recommended as an option for treating acute lymphoblastic leukaemia in children, young people and adults only when they have untreated newly diagnosed disease.	Formulary	A
409	Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion	September 2016	Aflibercept is recommended as an option within its marketing authorisation for treating visual impairment in adults caused by macular oedema after branch retinal vein occlusion, only if the company provides aflibercept with the discount agreed in the patient access scheme.	Formulary	A
410	Talimogene laherparepvec for treating unresectable metastatic melanoma	September 2016	Talimogene laherparepvec is recommended, in adults, as an option for treating unresectable, regionally or distantly metastatic (Stage IIIB, IIIC or IVM1a) melanoma that has not spread to bone, brain, lung or other internal organs, only if: • treatment with systemically administered immunotherapies is not suitable and • the company provides talimogene laherparepvec with the discount agreed in the patient access scheme.	Formulary	A
411	Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer	September 2016	Necitumumab, in combination with gemcitabine and cisplatin, is **not recommended** within its marketing authorisation for adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been treated with chemotherapy. .	Non-Formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
412	Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases	September 2016	Radium-223 dichloride is recommended as an option for treating hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases in adults, only if: • they have already had docetaxel or • docetaxel is contraindicated or is not suitable for them. The drug is only recommended if the company provides radium-223 dichloride with the discount agreed in the patient access scheme.	Patient treatment pathway not provided at St George's (commissioning decision)	C
413	Elbasvir–grazoprevir for treating chronic hepatitis C	October 2016	Elbasvir–grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.	Formulary	A
414	Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma	October 2016	Cobimetinib in combination with vemurafenib is **not recommended** within its marketing authorisation for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation.	Non-Formulary	B

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
415	Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor	October 2016	Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor‑alpha (TNF‑alpha) inhibitor, only if: • disease activity is severe and • rituximab is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme. Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF‑alpha inhibitor, only if: • disease activity is severe and • rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
416	Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer	October 2016	Osimertinib is recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only: • after first-line treatment with an EGFR tyrosine kinase inhibitor and • if the conditions in the managed access agreement for osimertinib are followed.	Formulary	A
417	Nivolumab for previously treated advanced renal cell carcinoma	November 2016	Nivolumab is recommended, within its marketing authorisation, as an option for previously treated advanced renal cell carcinoma in adults, when the company provides nivolumab with the discount agreed in the patient access scheme.	Formulary	A
418	Dapagliflozin in triple therapy for treating type 2 diabetes	November 2016	Dapagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in adults, only in combination with metformin and a sulfonylurea.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator

419	Apremilast for treating moderate to severe plaque psoriasis	November 2016	Apremilast is recommended as an option for treating chronic plaque psoriasis in adults whose disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and ultraviolet‑A light), or when these treatments are contraindicated or not tolerated, only if:
			• the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
			• treatment is stopped if the psoriasis has not responded adequately at 16 weeks; an adequate response is defined as:
			  • a 75% reduction in the PASI score (PASI 75) from when treatment started or
			  • a 50% reduction in the PASI score (PASI 50) and a 5‑point reduction in DLQI from start of treatment
			• the company provides apremilast with the discount agreed in the patient access scheme.
			
			When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.
				Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
420	Ticagrelor for preventing atherothrombotic events after myocardial infarction	December 2016	Ticagrelor, in combination with aspirin, is recommended within its marketing authorisation as an option for preventing atherothrombotic events in adults who had a myocardial infarction and who are at high risk of a further event.	Formulary	A
421	Everolimus with exemestane for treating advanced breast cancer after endocrine therapy	December 2016	Everolimus, in combination with exemestane, is recommended within its marketing authorisation, as an option for treating advanced human epidermal growth factor receptor 2 (HER2)-negative, hormone-receptor-positive breast cancer in postmenopausal women without symptomatic visceral disease that has recurred or progressed after a non-steroidal aromatase inhibitor. Everolimus is recommended only if the company provides it with the discount agreed in the patient access scheme.	Formulary	A
422	Crizotinib for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	December 2016	Crizotinib is recommended, within its marketing authorisation, as an option for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer in adults. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
423	Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens	December 2016	Eribulin is recommended as an option for treating locally advanced or metastatic breast cancer in adults, only when: • it has progressed after at least 2 chemotherapy regimens (which may include an anthracycline or a taxane, and capecitabine) • the company provides eribulin with the discount agreed in the patient access scheme.	Formulary	A
424	Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer	December 2016	Pertuzumab, in combination with trastuzumab and chemotherapy, is recommended, within its marketing authorisation, as an option for the neoadjuvant treatment of adults with human epidermal growth factor receptor 2 (HER2)‑positive breast cancer; that is, in patients with HER2-positive, locally advanced, inflammatory or early-stage breast cancer at high risk of recurrence. It is recommended only if the company provides pertuzumab with the discount agreed in the patient access scheme.	Formulary	A

NICE TECHNOLOGY APPRAISAL MEDICINES REPORT 2015 – 2016

Ref	TA Title	Date Issued	Guidance	Formulary status 3 months after publication	Compliance indicator
425	Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia	December 2016	Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if: • they cannot have imatinib, or their disease is imatinib-resistant and • the companies provide the drugs with the discounts agreed in the relevant patient access schemes. High-dose imatinib (that is, 600 mg in the chronic phase or 800 mg in the accelerated and blast-crisis phases) is **not recommended** for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant.	Formulary	A
426	Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia	December 2016	Imatinib is recommended as an option for untreated, chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults. Dasatinib and nilotinib are recommended, within their marketing authorisations, as options for untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults. The drugs are recommended only if the companies provide them with the discounts agreed in the relevant patient access schemes.	Formulary	A