Formulary Adherence Checklist for NICE Technology Appraisals About Medicines

Milton Keynes Health Economy

Developed for the NHS by: **East and South East England Specialist Pharmacy Services**

This spreadsheet is updated monthly and enables self-audit of a medicines formulary for adherence to current NICE Technology Appraisals. Version 8 April 2016
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Technology appraisal (TA) Titles are hyperlinks to full guidance	***Date of TA Release***	***Availability of medicine for NHS patients with this medical condition, as indicated by NICE***	***Adherence of local formulary to NICE***				
			Yes *(mark 'x' if applicable)*	***N/A*** *(mark 'x' if applicable)*	***Date of local decision*** *(DD/MM/YY)*	***Time to implement*** *(days)*	***Notes*** *(e.g. rationale, method of making available)*
2015/2016							
Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis [TA386]	23/03/2016	**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.	x		06/04/2016	14	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.
Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia [TA385]	24/02/2016	**Ezetimibe** monotherapy is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults in whom initial statin therapy is contraindicated or is not tolerated. Ezetimibe, co-administered with statin therapy, is recommended as an option when serum total or low-density lipoprotein (LDL) cholesterol concentration is not appropriately controlled (see full guidance for details) and a change from initial statin therapy to an alternative statin is being considered.	x		06/04/2016	42	The guidance should be used with NICE's guidelines on 'cardiovascular disease: risk assessment and reduction, including lipid modification' and 'familial hypercholesterolaemia: identification and management'. When prescribing ezetimibe co-administered with a statin, ezetimibe should be prescribed on the basis of lowest acquisition cost. For the purposes of this guidance, intolerance to initial statin therapy is defined as the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy. For the purposes of this guidance, appropriate control of cholesterol concentrations should be based on individual risk assessment according to national guidance on managing cardiovascular disease in the relevant populations.
Nivolumab for treating advanced (unresectable or metastatic) melanoma [TA384]	18/02/2016	**Nivolumab** as monotherapy is recommended as an option for treating advanced (unresectable or metastatic) melanoma in adults.	x		06/04/2016	48	NHSE commissioned

TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis [TA383]	01/02/2016	**Adalimumab, certolizumab pegol, etanercept, golimumab** and **infliximab** are recommended as options for treating severe active ankylosing spondylitis, and **adalimumab, certolizumab pegol** and **etanercept** are recommended 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.	x		06/04/2016	65	Infliximab is recommended only if treatment is started with the least expensive infliximab product. 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. Treatment should only be continued if there is clear evidence of response (see full guidance for details). Treatment with another 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. When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate.
Eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy (terminated appraisal) [TA382]	27/01/2016	**Eltrombopag** - unable to make a recommendation because no evidence submission was received from Novartis for the technology.	x		06/04/2016	70	Appraisal terminated.
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 (TA381)	27/01/2016	**Olaparib** is recommended 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.	x		06/04/2016	70	NHSE commissioned. Only if patients 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.
Panobinostat for treating multiple myeloma after at least 2 previous treatments (TA380)	27/01/2016	**Panobinostat** in combination with bortezomib and dexamethasone is recommended as an option for treating multiple myeloma	x		06/04/2016	70	NHSE commissioned. 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 PAS.

Nintedanib for treating idiopathic pulmonary fibrosis [TA379]	27/01/2016	**Nintedanib** is recommended as an option for treating idiopathic pulmonary fibrosis	x		06/04/2016	70	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 PAS, and treatment is stopped if disease progresses (a confirmed decline in percent predicted FVC of 10% or more) in any 12-month period.
Ramucirumab for treating advanced gastric cancer or gastro–oesophageal junction adenocarcinoma previously treated with chemotherapy (TA378)	27/01/2016	**Ramucirumab** alone or with paclitaxel is not recommended for advanced gastric cancer or gastro–oesophageal junction adenocarcinoma previously treated with chemotherapy.		x	06/04/2016	70	Not recommended
Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated [TA377]	27/01/2016	**Enzalutamide** is recommended as an option for treating metastatic hormone-relapsed prostate cancer	x		06/04/2016	70	NHSE commissioned. 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 PAS.
Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (TA376)	27/01/2016	**Radium-223 dichloride** is recommended as an option for treating adults with hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases.		x	06/04/2016	70	NHSE commissioned. Only if previous treatment with docetaxel, and the company provides radium-223 dichloride with the discount agreed in the PAS.
Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed [TA375]	26/01/2016	**Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab** and **abatacept**, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, and adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance.	x		06/04/2016	71	Only if disease is severe (i.e. a disease activity score (DAS28) >5.1 and has not responded to intensive therapy with a combination of conventional DMARDs), and the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their PAS's. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules.

Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy [TA374]	16/12/2015	**Erlotinib** - recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours of unknown EGFR-TK mutation status (see notes for conditions of the recommendation), but is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative. **Gefitinib** - not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive.	x		26/01/2016	41	NHSE commissioned. Prescribing to follow east midlands cancer network protocols Add to the formulary (RED)
Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis [TA373]	16/12/2015	**Abatacept, adalimumab, etanercept and tocilizumab** - recommended as possible treatments for polyarticular juvenile idiopathic arthritis. **Adalimumab and etanercept** - recommended as possible treatments for enthesitis-related juvenile idiopathic arthritis. **Etanercept** - recommended as a possible treatment for psoriatic juvenile idiopathic arthritis.	x		26/01/2016	41	NHSE commissioned. Prescribing to follow SSC advice Add to the formulary (RED)
Apremilast for treating active psoriatic arthritis [TA372]	16/12/2015	**Apremilast -** not recommended for treating adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or such therapy is not tolerated.	x		26/01/2016	41	Not recommended by NICE – no action
Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane [TA371]	16/12/2015	**Trastuzumab emtansine**- not recommended for treating adults with human epidermal growth factor 2 (HER2) positive, unresectable locally advanced or metastatic breast cancer previously treated with trastuzumab and a taxane.	x		26/01/2016	41	Not recommended by NICE – no action
Bortezomib for previously untreated mantle cell lymphoma [TA370]	16/12/2015	**Bortezomib** - recommended as an option for previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable	x		26/01/2016	41	NHSE commissioned. Prescribing to follow east midlands cancer network protocols Add to the formulary (RED)
Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears [TA369]	16/12/2015	**Ciclosporin -** recommended as an option for treating severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes.	x		26/01/2016	41	Agreed to add to the formulary for consultant initiation only and for at least one month (RED).
Apremilast for treating moderate to severe plaque psoriasis [TA368]	25/11/2015	**Apremilast** - not recommended for treating moderate to severe chronic plaque psoriasis that has not responded to systemic therapy, or systemic therapy is contraindicated or not tolerated.	x		26/01/2016	62	Not recommended by NICE – no action

Vortioxetine for treating major depressive episodes [TA367]	25/11/2015	**Vortioxetine -** recommended as an option for treating major depressive episodes in adults whose condition has responded inadequately to 2 antidepressants within the current episode.	x		26/01/2016	62	Drug funding review. Agreed to add to formulary for hospital use only (RED).
Pembrolizumab for advanced melanoma not previously treated with ipilimumab [TA366]	25/11/2015	**Pembrolizumab** - recommended as an option for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab.	x		26/01/2016	62	NHSE commissioned. Prescribing to follow east midlands cancer network protocols Add to the formulary (RED)
Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C [TA365]	25/11/2015	**Ombitasvir–paritaprevir–ritonavir** - recommended with or without dasabuvir, as an option for treating genotype 1 or 4 chronic hepatitis C.	x		26/01/2016	62	Hepatitis C service not currently in commission in MK – No action
Daclatasvir for treating chronic hepatitis C [TA364]	25/11/2015	**Daclatasvir** - recommended as an option for treating chronic hepatitis C.	x		26/01/2016	62	Hepatitis C service not currently in commission in MK – No action
Ledipasvir–sofosbuvir for treating chronic hepatitis C [TA363]	25/11/2015	**Ledipasvir–sofosbuvir** - recommended as an option for treating chronic hepatitis C.	x		26/01/2016	62	Hepatitis C service not currently in commission in MK – No action
Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer [TA362]	28/10/2015	**Paclitaxel** - unable to make a recommendation because no evidence submission was received from Celgene for the technology.	x		26/01/2016	90	Appraisal terminated by NICE - no action.
Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C [TA361]	28/10/2015	**Simeprevir** in combination with sofosbuvir - unable to make a recommendation because no evidence submission was received from Janssen for the technology.	x		25/11/2015	28	Terminated Appraisal by NICE - no action.
Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer [TA360]	28/10/2015	**Paclitaxel** as albumin-bound nanoparticles (nab-Paclitaxel) in combination with gemcitabine - not recommended for adults with previously untreated metastatic adenocarcinoma of the pancreas.	x		25/11/2015	28	Not recommended by NICE – no action
Idelalisib for treating chronic lymphocytic leukaemia [TA359]	28/10/2015	**Idelalisib** - recommended in combination with rituximab as a treatment for chronic lymphocytic leukaemia (CLL)	x		25/11/2015	28	Approved for formulary inclusion in line with NICE TA359
Tolvaptan for treating autosomal dominant polycystic kidney disease [TA358]	28/10/2015	**Tolvaptan -** recommended as an option for treating autosomal dominant polycystic kidney disease in adults to slow the progression of cyst development and renal insufficiency	x		25/11/2015	28	Add to the formulary. Should be initiated on advice of a renal consultant or a tertiary centre, strictly in line with NICE TA358. It will be treated as a High Cost Drug in order to be purchased at the Patient Access Scheme price. Hosptial Prescribing only
Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab (TA357)	07/10/2015	**Pembrolizumab** - recommended as an option for treating advanced (unresectable or metastatic) melanoma.	x		25/11/2015	49	Approved for formulary inclusion to be used in line with NICE TA357
Ruxolitinib for treating polycythaemia vera (TA356)	30/09/2015	**Ruxolitinib -** unable to make a recommendation because no evidence submission was received from Novartis Pharmaceuticals for the technology.	x		25/11/2015	56	Terminated Appraisal by NICE - no action.
Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation (TA355)	30/09/2015	**Edoxaban** - recommended as an option for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation with one or more risk factors (congestive heart failure, hypertension, diabetes, prior stroke or transient ischaemic attack, age ≥75 years)	x		25/11/2015	56	Approved for formulary inclusion in line with NICE TA355. Its place in therapy needs further review and local agreement.

Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism (TA354)	31/08/2015	**Edoxaban** - recommended as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.	x		25/11/2015	86	Approved for formulary inclusion in line with NICE TA354. Its place in therapy needs further review and local agreement.
Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (TA353)	31/08/2015	**Bevacizumab** - unable to make a recommendation because no evidence submission was received from Roche Products for the technology.	x		25/11/2015	86	Terminated Appraisal by NICE - no action.
Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy (TA352)	31/08/2015	**Vedolizumab** - recommended as an option for treating moderately to severely active Crohn's disease	x		25/11/2015	86	Approved for formulary inclusion to be used in line with NICE TA352
Cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti-platelet therapy (TA351)	31/07/2015	**Cangrelor** - unable to make a recommendation because no evidence submission was received from The Medicines Company UK for the technology.	x		23/09/2015	54	Terminated Appraisal by NICE - no action.
Secukinumab for treating moderate to severe plaque psoriasis (TA350)	31/07/2015	**Secukinumab** - recommended as an option for treating adults with plaque psoriasis	x		23/09/2015	54	Secukinumab (Cosentyx®) injection was approved for formulary inclusion for treating moderate to severe plaque psoriasis. A NICE compliance form to be developed.
Dexamethasone intravitreal implant for treating diabetic macular oedema (TA349)	31/07/2015	**Dexamethasone intravitreal implant** - recommended as an option for treating diabetic macular oedema	x		23/09/2015	54	Dexamethasone 700 micrograms intravitreal implant was approved for formulary inclusion for treating diabetic macular oedema
Everolimus for preventing organ rejection in liver transplantation (TA348)	31/07/2015	**Everolimus -** not recommended for preventing organ rejection in people having a liver transplant.	x		23/09/2015	54	Not recommended
Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer (TA347)	31/07/2015	**Nintedanib** - recommended in combination with docetaxel as an option for treating locally advanced, metastatic or locally recurrent non-small-cell lung cancer of adenocarcinoma histology that has progressed after first-line chemotherapy	x		23/09/2015	54	Nintedanib (Vargatef®) Capsules was approved for formulary inclusion for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer.
Aflibercept for treating diabetic macular oedema (TA346)	31/07/2015	**Aflibercept solution for injection** - recommended as an option for treating visual impairment caused by diabetic macular oedema	x		23/09/2015	54	Aflibercept (Eylea®) solution for injection was approved for formulary inclusion for treating visual impairment caused by diabetic macular oedema.
Naloxegol for treating opioid-induced constipation (TA345)	31/07/2015	**Naloxegol** - recommended as an option for treating opioid induced constipation in adults whose constipation has not adequately responded to laxatives.	x		23/09/2015	54	Naloxegol (Moventig®) Tablets was approved for formulary inclusion for treating opioid-induced constipation.

Ofatumumab in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia (TA344)	30/06/2015	**Ofatumumab** - recommended in combination with chlorambucil as an option for untreated chronic lymphocytic leukaemia.	x		22/07/2015	22	NHS England funded. Ofatumumab was approved for formulary inclusion for use in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia in accordance with NICE TA 344
Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia (TA343)	30/06/2015	**Obinutuzumab** - recommended in combination with chlorambucil, as an option for adults with untreated chronic lymphocytic leukaemia who have comorbidities that make full-dose fludarabine-based therapy unsuitable for them.	x		22/07/2015	22	NHS England funded. Obinutuzumab (Gazyvaro▼) was approved for formulary inclusion for use in combination with chlorambucil for untreated chronic lymphocytic leukaemia in accordance with NICE TA 343.
Vedolizumab for treating moderately to severely active ulcerative colitis (TA342)	30/06/2015	**Vedolizumab** - recommended as an option for treating moderately to severely active ulcerative colitis (UC) in adults.	x		22/07/2015	22	Approved for formulary inclusion for treating severely active ulcerative colitis in accordance with NICE TA 342. Treatment pathway in development.
Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism (TA341)	30/06/2015	**Apixaban** - recommended as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.	x		22/07/2015	22	Apixaban was approved for formulary inclusion for treating and preventing recurrent deep vein thrombosis or pulmonary embolism in accordance with NICE TA 341. The current local agreement on the use of novel oral anticoagulants can be found on the formulary website at: http://formularymk.nhs.uk/includes/documents/NOACs-MKPAG-Summary-July2014-1.pdf
Ustekinumab for treating active psoriatic arthritis (rapid review of technology appraisal guidance 313) (TA340)	30/06/2015	**Ustekinumab** - recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults	x		22/07/2015	22	Approved for formulary inclusion for the treatment of psoriatic arthritis in accordance with NICE TA 340. Prescribing by consultant Rheumatologists and Dermatologists only. Develop a NICE compliance form for ustekinumab use in line with NICE TA340 defining its place in therapy vs other similar agents.
Omalizumab for previously treated chronic spontaneous urticaria (TA339)	30/06/2015	**Omalizumab**- recommended as an option as add-on therapy for treating severe chronic spontaneous urticaria in adults and young people aged 12 years and over.	x		22/07/2015	22	Approved for formulary inclusion in line with NICE TA339. It is not for initiation or routine continuation. Clinician may prescribe it in exceptional circumstances to patients to ensure continuity of supply while arrangements are made to obtain on-going supplies from specialist secondary care centre.
			45	2			
			% "Yes"	**% "N/A"**	_	**Average implement time** (days)	
Adherence statistics for 2014-15			96%	4%		**52**	