



AWTTC

All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Medicines not considered suitable for the One Wales Medicines Process January 2022

Medicine	Indication	One Wales decision rationale*	AWMSG Steering Committee Date
Apremilast (Otezla®)	Psoriasis/ psoriatic arthritis	NICE recommended, all IPFR requests pre NICE advice	26/04/2016
Arsenic trioxide (TRISENOX®)	Acute promyelocytic leukaemia (relapsed/refractory)	On consultation with experts there is no unmet clinical need for this licensed indication.	22/08/2016
Atorvastatin (Lipitor®)	Hypercholesterolaemia	No unmet clinical need identified	04/07/2017
Belimumab (Benlysta®)	Systemic lupus erythamatosus (SLE)	NICE restricted recommendation, TA397, published June 2016.	15/08/2017
Bendamustine	Multiple myeloma (3rd and 4th line)	Licensed alternative (pomalidomide) recommended by AWMSG, Aug 2015. Monitor for further requests post recommendation.	22/08/2016
Bevacizumab (Avastin®)	Carcinoma of cervix	HTA in progress with AWMSG	17/10/2016
Bevacizumab (Avastin®)	Ovarian cancer 2nd and 3rd line	AWMSG HTA pending	22/08/2016
Bevacizumab (Avastin®)	Colorectal cancer	NICE negative recommendation	21/06/2016
Bevacizumab (Avastin®)	Vestibular schwannoma	WHSSC will publish a commissioning policy with support from AWTTC.	26/09/2017

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Medicines not considered suitable for the One Wales Medicines Process January 2022 continued

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Biologic therapy	Psoriasis	No unmet clinical need identified. This is not an interim commissioning request.	27/02/2018
Bisphosphonates	Adjuvant therapy for breast cancer in post-menopausal women to reduce risk of metastases to bones	Clinical network issue	17/10/2016
Budesonide (Jorveza®)	Eosinophilic oesophagitis in children <18 years	Suitable for local health board decision	27/01/2020 (Chair's action)
Certolizumab pegol (Cimzia®)	Rheumatoid arthritis	NICE restricted recommendation, TA415, published Oct 2016.	15/08/2017
Cetuximab (Erbix®)	Colorectal cancer 1st line	AWMSG restricted recommendation, Dec 2015, all IPFR requests pre AWMSG advice, or within 3 months.	21/06/2016
Cetuximab (Erbix®)	Colorectal cancer 2nd/3rd/4th line	NICE negative recommendation	21/06/2016
Cinacalcet (Mimpara®)	Primary hyperparathyroidism	Suitable for AWMSG HTA, submission requested.	04/07/2017
co-careldopa (Duodopa®)	Parkinson's disease	Will be considered as part of the AWMSG HTA review	21/07/2016
Daratumumab (DARZALEX®)	Multiple myeloma relapsed/refractory > 3rd line monotherapy	HTA in progress with NICE, ID933 appraisal consultation document issued. Final appraisal determination date TBC.	26/09/2017

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Daratumumab (DARZALEX®)	Multiple myeloma relapsed/refractory in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone	No commitment to engage with HTA	26/09/2017
Dasatinib (Sprycel®)	Chronic myelocytic leukaemia, 2nd and 3rd line	NICE rapid review in progress	17/10/2016
Daunorubicin and cytarabine with gemtuzumab ozogamicin	Off-label AML trial regimen for gentuzumab ozogamicin in combination with daunorubicin and cytarabine for untreated de novo CD33-positive acute myloid leukaemia (AML).	Licensed regimen recommended by NICE. Nov 2018	27/01/2020 (Chair's action)
Enzalutamide (Xtandi®)	Prostate cancer	NICE recommended, all IPFR requests pre NICE advice	21/06/2016
Eribulin (Halaven®)	Metastatic breast cancer 4th and 5th line	Undergoing re-appraisal with NICE	17/10/2016
Everolimus (Afinitor®)	Tuberous sclerosis with renal angioderma (paeds)	No patient cohort identified	17/10/2016
Everolimus (Afinitor®)	Renal cell carcinoma/ renal cancer	Available to use in Wales since Nov 2015, no IPFRs since Welsh Government agreement.	21/06/2016
Everolimus (Votubia®)	Treatment of: Renal angiomyolipoma associated with tuberous sclerosis complex (TSC); Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC); Refractory seizures associated with tuberous sclerosis complex (TSC)	Suitable for AWMSG HTA, submission requested.	05/06/2018

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Evolocumab (Repatha®)	Familial hypercholesterolaemia	NICE in progress, final appraisal determination published April 2016, positive recommendation.	21/06/2016
Fulvestrant (Faslodex®)	Breast cancer	NICE TA published	01/03/2016
GRAZAX 75,000 SQ-T oral lyphilisate	Treatment of grass pollen induced rhinitis and conjunctivitis in children (5 years or older)	Met exclusion criteria for HTA. For consideration by local health board formulary.	25/09/2018
Guanfacine (Intuniv®)	Treatment of ADHD in children where stimulants are not suitable	AWMSG negative advice	02/05/2017
Ibrutinib (Imbruvia®)	1st line treatment of chronic lymphocytic leukaemia (CLL) during COVID to avoid chemotherapy	An alternative oral chemotherapy-free option has been recommended by NICE	24/08/2021
Ibrutinib (Imbruvia®)	Waldenstrom's macroglobulinaemia	HTA in progress with NICE ID884. Appraisal consultation document issued. Final Appraisal determination date TBC.	26/09/2017
Ibrutinib (Imbruvia®)	Mantle cell lymphoma relapsed/refractory	HTA in progress with NICE ID753. Appraisal consultation document issued. Final Appraisal determination date TBC.	26/09/2017, 26/04/2016
Ibrutinib (Imbruvica®)	Chronic lymphocytic leukaemia	HTA in progress with NICE	26/04/2016
Idebenone (Raxone®)	Treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy	AWMSG HTA pending	26/04/2016

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Insulin degludec (Tresiba®)	Type 1 diabetes; type 2 diabetes; hyperglycaemia	Re-submission in progress AWMSG advice expected Oct 2016	21/06/2016
Ivermectin (Stromectol®)	Strongyloides infection – acute or chronic	Current standard treatment according to national guidelines. Health boards should look at ways to facilitate access to treatment.	18/01/2022
Ixazomib (Ninlaro®)	In combination with lenalidomide and dexamethasone for relapsed or refractory multiple myeloma	HTA in progress with NICE, advice due Aug 2017	02/05/2017
Lenvantinib (Lenvima®)	Adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine	Suitable for AWMSG HTA, submission requested	22/08/2016
Nitisinone (Orfadin®)	AKU (Alkaptonuria)	WHSSC will publish a commissioning policy with support from AW TTC.	26/09/2017
Nivolumab (Opdivo®)	Advanced (unresectable or metastatic) melanoma in adults	NICE TA published Feb 2016	01/03/2016
Nivolumab (Opdivo®)	Squamous carcinoma lung / bronchus	In progress with NICE, company have re-submitted with a PAS post final appraisal determination (FAD withdrawn April 2016).	21/06/2016
Nivolumab (Opdivo®)	Renal cell cancer	NICE TA published Nov 2016	04/07/2017
Nivolumab (Opdivo®)	Non-small cell lung cancer	HTA in progress with NICE	15/08/2017

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Olanzapine depot (ZyAdhera®)	Resistant schizophrenia	AWMSG restricted recommendation published July 2016	21/06/2016
Olaratumab (Lartruvo®)	Advanced soft tissue sarcoma	HTA in progress with NICE	02/05/2017
Omalizumab (Xolair®)	Severe urticaria	NICE recommended, all IPFR requests pre NICE advice or within 3 month implementation window.	21/06/2016
Omalizumab (Xolair®)	Severe atopic eczema	On consultation with experts there is no unmet clinical need for this licensed indication.	17/10/2016, 26/09/2017
Pertuzumab (Perjeta®)	In combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence	HTA in progress with NICE	01/03/2016
Pertuzumab (Perjeta®)	In combination with trastuzumab and docetaxel for the treatment of HER2 positive metastatic or locally recurrent unresectable breast cancer, which has not been previously treated, or has relapsed after adjuvant therapy	HTA in progress with NICE	01/03/2016

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Pertuzumab (Perjeta®)	Treatment of HER2-positive metastatic breast cancer where treatment has already commenced with trastuzumab and docetaxel.	Lack of evidence to support practice. Not identified as an All-Wales unmet need.	03/07/2018
Pertuzumab (Perjeta®)	In combination with trastuzumab and docetaxel for the treatment of adult patients with HER2-positive, breast cancer at high risk of recurrence	HTA in progress with NICE	15/08/2017
Praziquantel	Schistosomiasis	Current standard treatment according to national guidelines. Health boards should look at ways to facilitate access to treatment.	18/01/2022
Rituximab (Mabthera®)	Idiopathic thrombocytopenic purpura	No unmet clinical need identified	02/05/2017
Rituximab (Mabthera®)	Waldenstrom's macroglobulinaemia/ rare b cell lymphomas	Suitable licensed alternatives available	17/10/2016
Rituximab (Mabthera®)	Dermatomyositis and polymyositis	No clinical unmet need identified.	26/09/2017
Rituximab (MabThera®)	Systemic lupus erythamatosus (non-renal)	No clinical unmet need identified and suitable licensed alternative available	26/09/2017
Rituximab (Mabthera®) + bendamustine	Chronic lymphocytic lymphoma	On consultation with experts there is no unmet clinical need for this licensed indication	04/07/2017

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Ruxolitinib (Jakavi®)	Myelofibrosis	NICE recommended, all IPFR requests pre NICE advice	21/06/2016
Secukinumab (Cosentyx®)	Psoriatic arthritis	HTA in progress with NICE	04/07/2017
Sodium oxybate (Xyrem®)	Narcolepsy with cataplexy	Licensed with SOA	17/10/2016
Sofosbuvir (Sovaldi®)	Hepatitis C	NICE recommended, all IPFR requests pre NICE advice	21/06/2016
Sofosbuvir/velpatasvir (Epclusa®)	Chronic Hepatitis C in adults	HTA in progress with AWMSG advice due Nov 2016	22/08/2016
Sorafenib (Nexavar®)	Hepatocellular carcinoma	AWMSG restricted recommendation, all IPFR requests pre AWMSG advice	21/06/2016
Tenofovir alafenamide	HIV	HTA in progress with AWMSG	26/04/2016
Teriparatide (Forsteo®)	Osteoporosis	AWTTC in discussion with company to consider resubmission to AWMSG	22/08/2016
Tocilizumab (Roactemra®)	Seropositive rheumatoid arthritis	NICE recommended, all IPFR requests pre NICE advice	21/06/2016
Tocilizumab (Roactemra®)	Giant cell arteritis	No patient cohort identified	04/07/2017

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Medicines not considered suitable for the One Wales Medicines Process January 2022 continued

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Trastuzumab emtamsine (Kadcyla®)	As a single agent, for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy	NICE negative recommendation	01/03/2016
Ustekinumab (Stelara®)	Every 4 weeks for treatment of moderately to severely active Crohn's disease	Awaiting results of clinical trial. To continue monitoring for cohorts. Remains local decision.	24/08/2021
Vedolizumab (Entyvio®)	Crohn's disease	NICE recommended, all IPFR requests pre NICE advice	21/06/2016
Venetoclax (Venclyxto®)	Chronic lymphocytic leukaemia	HTA in progress with NICE	24/01/2017
Vismodegib (Erivedge®)	Basal cell carcinoma	Directed HTA in progress with AWMSG	22/08/2016

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