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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)*** |
| Bempedoic acid (*Nilemdo*)180mg tablet | Use in adults with established or at high risk for atherosclerotic cardiovascular (CV) disease to reduce CV risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in patients on a maximum tolerated dose of a statin with or without ezetimibe or, alone or in combination with ezetimibe in patients who are statin-intolerant, or for whom a statin is contraindicated [new indication] |
| Bempedoic acid + ezetimibe (*Nustendi*)180mg/10mg tablet | Use in adults with established or at high risk for atherosclerotic cardiovascular (CV) disease to reduce CV risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe treatment or, in patients who are either statin-intolerant, or for whom a statin is contraindicated, and not adequately controlled with ezetimibe treatment or, in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets [new indication] |
| Bictegravir + emtricitabine + tenofovir alafenamide (*Biktarvy*)30mg/120mg/15mg tablet | Treatment of human immunodeficiency virus-1 infection adults and paediatric patients aged ≥2 years and weighing ≥14kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir [new lower strength 30mg/120mg/15mg tablet formulation] |
| Bimekizumab (*Bimzelx*) 160mg in 1mL prefilled pen and prefilled syringe | Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy [new indication] |
| Bismuth subcitrate potassium + metronidazole + tetracycline (*Pylera*) 140mg/125mg/125mg capsule | Use in combination with omeprazole for the eradication of *Helicobacter pylori* and prevention of relapse of peptic ulcers in patients with active, or a history of, *H. pylori* associated ulcers [new formulation] |
| Cefepime + enmetazobactam (*Exblifep*) 2g/0.5g vial | Treatment of the following infections in adults: Complicated urinary tract infections including pyelonephritis, hospital-acquired pneumonia including ventilator associated pneumonia, and treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above |
| Dabrafenib (*Finlee*)10mg dispersible tablet | Use in combination with trametinib for the treatment of paediatric patients aged ≥1 year with low-grade glioma with a BRAF V600E mutation who require systemic therapy, and use in combination with trametinib for the treatment of paediatric patients aged ≥1 year with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment [new dispersible tablet formulation with a new indication] |
| Eculizumab biosimilar (*Epysqli*) 300mg in 30mL vial | Use in adults and children for the treatment of atypical haemolytic uraemic syndrome [new indication] |
| Enzalutamide (*Xtandi*)40mg tablet | Use as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer who are unsuitable for salvage radiotherapy [new indication] |
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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)* (continued)** |
| Human fibrinogen + human thrombin (*VeraSeal*)Single-use kit | Supportive treatment in patients of all ages where standard surgical techniques are insufficient: for improvement of haemostasis and as suture support in vascular surgery [licence change from use only in adults] |
| Human normal immunoglobulin (*Yimmugo*)5g in 50mL, 10g in 100mL and 20g in 200mL vials | Replacement therapy in adults, children, and adolescents aged 0 to 18 years in primary immunodeficiency syndromes with impaired antibody production and secondary immunodeficiencies in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure or serum IgG level of <4g/L. Also immunomodulation in adults, children, and adolescents aged 0 to 18 years in primary immune thrombocytopenia in patients at high risk of bleeding or prior to surgery to correct the platelet count, Guillain Barré syndrome, Kawasaki’s disease, chronic inflammatory demyelinating polyradiculoneuropathy and multifocal motor neuropathy. [new formulation] *Note: Currently available in Wales but not England, until it is accepted onto the wider NHS England procurement framework for immunoglobulins* |
| Ivermectin 3mg tablet | Treatment of gastrointestinal strongyloidiasis (anguillulosis), suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti, and sarcoptic scabies, in adults and children weighing ≥15kg [Exeltis formulation] |
| Lanadelumab (*Takhzyro*) 150mg in 1mL prefilled syringe | Routine prevention of recurrent attacks of hereditary angioedema in patients aged ≥2 years [new lower dose formulation] |
| Latanaprost (*Lotacryn*)50micrograms/mL eye drops in 2.5mL bottle | Reduction of elevated intraocular pressure (IOP) in adults (including the elderly) with open angle glaucoma and ocular hypertension, and reduction of elevated IOP in paediatric patients with elevated IOP and paediatric glaucoma [new preservative-free formulation] |
| Patiromer (*Veltassa*) 8.4g and 16.8g powder for oral suspension in sachets | Treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years [licence change from use only in adults] |
| Phenylephrine + ketorolac (*Omidria*) 40.6mg/11.5mg in 4mL vial | Use in adults for maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement surgery [new intraocular irrigation formulation] |
| Trametinib (*Spexotras*)0.05mg in 1mL powder for oral solution | Use in combination with dabrafenib for treatment of paediatric patients aged ≥1 year with low-grade glioma with a BRAF V600E mutation who require systemic therapy, and use in combination with dabrafenib for treatment of paediatric patients aged ≥1 year with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment |
| Voxelotor (*Oxbryta*) 500mg tablet | Treatment of haemolytic anaemia due to sickle cell disease in adults and paediatric patients aged ≥12 years as monotherapy or in combination with hydroxycarbamide |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| Oritavancin (*Tenkasi*)1,200mg vial | Treatment of acute bacterial skin and skin structure infections in adults [new 1,200mg vial formulation] |
| Patiromer (*Veltassa*) 1g powder for oral suspension in sachets | Treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years [new lower 1g strength formulation] |
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| **Regulatory changes in the UK or EU**  |
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| ***Recommended for approval in the UK or EU*** |
| Adrenaline (*Eurneffy*) | Use in the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children with a body weight ≥30kg [EU] [new intranasal formulation] |
| Crizotinib (*Xalkori*) | Monotherapy for first‑line treatment of adults with anaplastic lymphoma kinase (ALK)‑positive advanced non‑small cell lung cancer (NSCLC), treatment of adults with previously treated ALK‑positive advanced NSCLC; treatment of adults with ROS1‑positive advanced NSCLC; treatment of paediatric patients (aged ≥1 to 17 years) with relapsed or refractory systemic ALK‑positive anaplastic large cell lymphoma (ALCL); treatment of paediatric patients (age ≥1 to 17 years) with recurrent or refractory ALK‑positive unresectable inflammatory myofibroblastic tumour (IMT) [EU] [licence change from use only in children aged ≥6 years with ALCL and IMT] |
| Crovalimab (*PiaSky*) | Use as monotherapy for the treatment of adult and paediatric patients aged ≥12 years with a weight ≥40kg with paroxysmal nocturnal haemoglobinuria, in patients with haemolysis with clinical symptom(s) indicative of high disease activity, and in patients who are clinically stable after having been treated with a complement component 5 inhibitor for at least the past 6 months [EU] |
| Durvalumab (*Imfinzi*) | Use in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer​ who are candidates for systemic therapy, followed by maintenance treatment with *Imfinzi* as monotherapy in endometrial cancer that is mismatch repair deficient, or in combination with olaparib in endometrial cancer that is mismatch repair proficient [EU] [new indication] |
| Epcoritamab (*Tepkinly*) | Use as monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy [EU] [new indication] |
| Erdafitinib (*Balversa*) | Use as monotherapy for the treatment of adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting [EU] |
| Faricimab (*Vabysmo*) | Treatment of adults with neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, and visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) [EU] [licence change to include treatment of visual impairment due to macular oedema secondary to retinal vein occlusion] |
| Isavuconazole (*Cresemba*) | Use in adults and in paediatric patients aged ≥6 years for the treatment of invasive aspergillosis and mucormycosis in patients for whom amphotericin B is inappropriate [EU] [new 40mg capsule formulation intended to be used for paediatric patients] |
| Isavuconazole (*Cresemba*) | Use in patients aged ≥1 year for the treatment of invasive aspergillosis and mucormycosis in patients for whom amphotericin B is inappropriate [EU] [licence change for the intravenous formulation from use only in adults] |
| Mirabegron (*Betmiga*) | Treatment of neurogenic detrusor overactivity in paediatric patients aged 3 to 17 years [EU] [new indication for prolonged-release tablets and new granules for prolonged-release oral suspension formulation] |
| Nirsevimab (*Beyfortus*) | Prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season [EU] [licence change from use only in a neonate´s or an infant´s first RSV season] |
| Odronextamab (*Ordspono*) | Use as monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy, and as monotherapy for the treatment of adults with relapsed or refractory diffuse large B‑cell lymphoma after two or more lines of systemic therapy [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Recommended for approval in the UK or EU* (continued)** |
| Olaparib (*Lynparza*) | Use in combination with durvalumab for the maintenance treatment of adults with primary advanced or recurrent endometrial cancer that is mismatch repair proficient whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel [EU] [new indication] |
| Peginterferon alpha 2a (*Pegasys*) | Use as monotherapy in adults for the treatment of polycythaemia vera, and use as monotherapy in adults for the treatment of essential thrombocythaemia [EU] [new indications] |
| Respiratory syncytial virus vaccine (*mResvia*) | Active immunisation for the prevention of lower respiratory tract disease caused by Respiratory Syncytial Virus in adults aged ≥60 years [EU] |
| Setmelanotide (*Imcivree*) | Treatment of obesity and the control of hunger associated with genetically confirmed Bardet‑Biedl syndrome, loss-of-function biallelic pro-opiomelanocortin, including PCSK1, deficiency or biallelic leptin receptor deficiency in adults and children aged ≥2 years [EU] [licence change from use only in children aged ≥6 years] |
| Sotatercept (*Winrevair*) | Use in combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of PAH in adults with WHO Functional Class II to III, to improve exercise capacity [EU] |
| Ustekinumab biosimilar (*Steqeyma*) | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use alone or in combination with MTX, for treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate; and for treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies [EU] |
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| ***Filed for approval in the UK or EU*** |
| Dostarlimab (*Jemperli*) | Use in combination with chemotherapy for primary advanced or recurrent endometrial cancer in adults, including those with mismatch repair proficient or microsatellite stable tumours [EU] [licence change from use only in adults with mismatch repair deficient or microsatellite instability-high] |
| Nivolumab (*Opdivo*) | Multiple solid tumour indications as approved for *Opdivo* intravenous formulation [EU] [new subcutaneous formulation] |
| Pembrolizumab (*Keytruda*) | Use in combination with carboplatin and paclitaxel for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults [UK] [new indication] |
| Zanidatamab  | Treatment of previously treated, unresectable, locally advanced, or metastatic HER2-positive biliary tract cancer [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Other UK/EU developments*** |
| Atezolizumab (*Tecentriq*) | Platinum-sensitive ovarian cancer in adults, second-line with bevacizumab and platinum chemotherapy – development discontinued (lack of efficacy) |
| Fordadistrogene movaparvovec  | Duchenne muscular dystrophy in ambulatory male patients aged 4 to 7 years – development discontinued (lack of efficacy) |
| Imatinib  | Pulmonary arterial hypertension (WHO functional class II to IV) in adults, dry powder inhaler formulation – development discontinued (lack of efficacy) |
| Masitinib (*Masitinib AB Science*) | Amyotrophic lateral sclerosis in adults – not recommended for approval in EU |
| Pegcetacoplan (*Syfovre*) | Geographic atrophy caused by age-related macular degeneration in adults – not recommended for approval in EU |
| Ravulizumab (*Ultomiris*) | Atypical haemolytic uraemic syndrome and paroxysmal nocturnal haemoglobinuria, subcutaneous formulation – development discontinued (company decision) |
| SAR443820 | Early-stage amyotrophic lateral sclerosis in adults – development discontinued (lack of efficacy) |
| Trilaciclib (*Cosela*) | Inoperable advanced, triple-negative breast cancer in adults, adjunct preceding first-line chemotherapy – development discontinued (lack of efficacy) |
| Venetoclax (*Venclyxto*) | Relapsed or refractory, t(11;14)-positive multiple myeloma in adults – development discontinued (lack of efficacy) |
| Xevinapant  | Advanced, unresectable squamous cell carcinoma in adults ineligible for cisplatin, first-line with chemoradiotherapy – development discontinued (lack of efficacy) |
| Xevinapant | Locally advanced, resectable squamous cell carcinoma in high-risk adults ineligible for cisplatin, with radiotherapy – development discontinued (company decision) |
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