

# HTANGEL

KEEPING YOU UP-TO-DATE ON  
INTERNATIONAL HTA DECISIONS

## Issue 13: May 2024

### Forty-seven approvals this month!

This newsletter summarises final decisions from HTA bodies around the world from published reports in May 2024.

**Good news** for: **Dabrafenib/trametinib**, approved for BRAF V600E+ glioma in France and BRAF V600E+ anaplastic thyroid cancer in Wales; **Pembrolizumab**, approved for relapsed/refractory Hodgkin lymphoma in England, HER2+ gastric cancer in Wales and triple-negative breast cancer in France; **Remdesivir**, approved for COVID-19 in Scotland and England.

**Mixed news** for: **Niraparib/abiraterone acetate**, approved for metastatic castration-resistant BRCA 1/2+ prostate cancer in Germany but not in France.

**Bad news** for: **Dupilumab, abrocitinib and upadacitinib**, not approved for atopic dermatitis in children and adolescents in Brazil; **Ivacaftor/tezacaftor/elexacaftor**, not approved for F508del homozygous or heterozygous cystic fibrosis in Germany; **Rozanolixizumab**, not approved for myasthenia gravis in France.

“

#### 47 Approvals

12 with special arrangements  
2 with orphan drug status

“

#### 31 Not approved

#### 4 Excluded submissions

“

#### 5 Evidence reviews



### Pharmacological Technologies

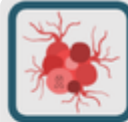


**Australia**  
TGA

**Blood**  
Haemophilia B  
Etranacogene  
dezaparvovec



Approved



**France**  
HAS AP309-330

**Cancer**  
Glioma  
Dabrafenib/  
trametinib



Approved



**Wales**  
AWTTC 5142

**Blood**  
PNH  
Iptacopan



Excluded



**Wales**  
AWTTC OW27

**Cancer**  
Thyroid cancer  
Dabrafenib/  
trametinib



Approved



**Brazil**  
CONITEC

**Cancer**  
Neuroblastoma  
Betadinutuximab



Not  
approved



**France**  
HAS AP315

**Cancer**  
Endometrial cancer  
Durvalumab and  
opalarib



Not  
approved



**Brazil**  
CONITEC

**Cancer**  
Head & neck cancer  
Cetuximab or  
pembrolizumab



Not  
approved



**Germany**  
IQWiG A24-30

**Cancer**  
Breast cancer  
Elacestrant



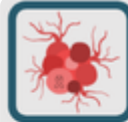
Approved

### Pharmacological Technologies



**Brazil**  
**CONITEC**

**Cancer**  
**Leukaemia**  
**Ibrutinib**



**Germany**  
**IQWiG A24-33**

**Cancer**  
**Prostate cancer**  
**Niraparib/abiraterone**  
**acetate**



**Germany**  
**IQWiG A23-110**

**Cancer**  
**Leukaemia**  
**Midostaurin**



**Brazil**  
**CONITEC**

**Cancer**  
**Head & neck cancer**  
**Nivolumab**



**Germany**  
**IQWiG G24-04**

**Cancer**  
**Myelofibrosis**  
**Momelotinib**



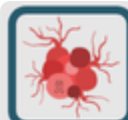
**England**  
**NICE TA540**

**Cancer**  
**Hodgkin lymphoma**  
**Pembrolizumab**



**France**  
**HAS AP314**

**Cancer**  
**Prostate cancer**  
**Niraparib/abiraterone**  
**acetate**



**England**  
**NICE TA967**

**Cancer**  
**Hodgkin lymphoma**  
**Pembrolizumab**



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## Pharmacological Technologies

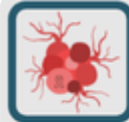


**Wales**  
AWTTC 4441

**Cancer**  
**Stomach cancer**  
**Pembrolizumab**



**Excluded**



**England**  
NICE TA970

**Cancer**  
**Multiple myeloma**  
**Selinexor/  
dexamethasone**



**Approved  
with special  
conditions**



**France**  
HAS AP160

**Cancer**  
**Breast cancer**  
**Pembrolizumab**



**Approved**



**France**  
HAS AP351

**Cancer**  
**Thyroid cancer**  
**Selpercatinib**



**Approved**



**Germany**  
IQWiG A24-16

**Cancer**  
**Leukaemia**  
**Quizartinib**



**Not  
approved**



**Germany**  
IQWiG A24-22

**Cancer**  
**Prostate cancer**  
**Talazoparib**



**Not  
approved**

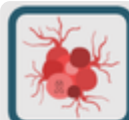


**England**  
NICE TA974

**Cancer**  
**Multiple myeloma**  
**Selinexor/ bortezomib/  
dexamethasone**



**Approved  
with special  
conditions**



**England**  
NICE TA975

**Cancer**  
**Leukaemia**  
**Tisagenlecleucel**



**Approved  
with special  
conditions**



### Pharmacological Technologies



**Tunisia**  
**INEAS c1309**

**Cancer**  
**Melanoma**  
**Vemurafenib**



**Germany**  
**IQWiG A23-101**

**Eye**  
**AMD**  
**Brolucizumab**



**Scotland**  
**SMC2671**

**Cancer**  
**Follicular lymphoma**  
**Zanubrutinib/  
obinutuzumab**



**Germany**  
**IQWiG A24-14**

**Genitourinary**  
**Hyperkalaemia**  
**Patiromer**



**Brazil**  
**CONITEC**

**Cardiovascular**  
**Amyloid cardiomyopathy**  
**Tafamidis**



**Wales**  
**AWTTC 3014**

**Genitourinary**  
**Anaemia**  
**Vadadustat**



**Germany**  
**IQWiG A23-112**

**Endocrine**  
**Type 2 diabetes**  
**Tirzepatide**



**Brazil**  
**CONITEC**

**Infection**  
**Brucellosis**  
**Gentamicin  
sulfate/doxycycline**



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## Pharmacological Technologies



France  
HAS AP319

Infection  
Malaria  
Primaquine  
phosphate

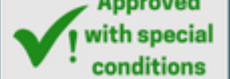


Approved



England  
NICE TA971

Infection  
COVID-19  
Remdesivir or  
tixagevimab/cilgavimab



Approved  
with special  
conditions



Australia  
TGA

Infection  
RSV  
Recombinant RSV pre-  
fusion F protein bivalent  
vaccine



Approved



Scotland  
SMC2558

Infection  
COVID-19  
Tixagevimab and  
cilgavimab



Not  
approved



Scotland  
SMC2550

Infection  
COVID-19  
Remdesivir



Approved



Germany  
IQWiG A23-122

Metabolic/genetic  
Cystic fibrosis  
Ivacaftor/tezacaftor/  
elexacaftor



Not  
approved



England  
NICE NG191

Infection  
COVID-19  
Remdesivir or  
tixagevimab



Approved  
with special  
conditions



Germany  
IQWiG A23-123

Metabolic/genetic  
Cystic fibrosis  
Ivacaftor/tezacaftor/  
elexacaftor



Not  
approved



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## Pharmacological Technologies



France  
HAS AP332

Metabolic/genetic  
Hyperarginaemia  
Pegzilarginase



Approved



Brazil  
CONITEC

Musculoskeletal  
Acromegaly  
Pegvisomant



Not  
approved



Australia  
TGA

Metabolic/genetic  
Hyperkalaemia  
Sodium zirconium  
cyclosilicate hydrate



Approved



Germany  
IQWiG A21-131

Musculoskeletal  
Spinal muscular atrophy  
Risdiplam



Approved  
orphan drug  
status



France  
HAS AP337

Metabolic/genetic  
Duchenne muscular  
dystrophy  
Vamorolone



Not  
approved



Brazil  
CONITEC

Musculoskeletal  
Osteoporosis  
Romosozumab



Approved



Brazil  
CONITEC

Musculoskeletal  
Acromegaly  
Pasireotide pamoate



Approved



Brazil  
CONITEC

Musculoskeletal  
Osteoporosis  
Teriparatide



Approved



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## Pharmacological Technologies



England  
NICE TA973

Neurology  
Migraine  
Atogepant



Approved



France  
HAS AP344

Neurology  
Myasthenia gravis  
Rozanolixizumab



Not  
approved



France  
HAS AP329

Neurology  
Myasthenia gravis  
Efgartigimod alfa



Not  
approved



Scotland  
SMC2622

Respiratory  
Asthma  
Budesonide/  
formoterol



Approved



Wales  
AWTTC 5285

Neurology  
Parkinson's disease  
Opicapone



Approved



Brazil  
CONITEC

Respiratory  
COPD  
Beclomethasone/  
formoterol/  
glycopyrronium bromide



Not  
approved



Brazil  
CONITEC

Neurology  
Parkinson's & dementia  
Rivastigmine



Approved



Brazil  
CONITEC

Respiratory  
COPD  
Fluticasone furoate/  
umeclidinium bromide/  
vilanterol triphenatate



Not  
approved



### Pharmacological Technologies



**Brazil**  
**CONITEC**

**Skin**

**Atopic dermatitis**

Abrocitinib, upadacitinib,  
dupilumab and  
baricitinib



**Scotland**  
**SMC2634**

**Skin**

**Vitiligo**

**Ruxolitinib**



**Australia**  
**TGA**

**Skin**

**Acne vulgaris**

**Clascoterone**



**Brazil**  
**CONITEC**

**Skin**

**Atopic dermatitis**

Dupilumab, abrocitinib  
and upadacitinib



**Wales**  
**AWTTC 4437**

**Skin**

**Atopic dermatitis**

**Lebrikizumab**



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## Non-pharmacological Technologies



England  
NICE IPG788

**Cancer**  
Liver cancer  
Image-guided  
percutaneous laser  
ablation



South Korea  
NECA

**Genitourinary**  
BPH  
Temporary implantable  
nitinol device



England  
NICE IPG786

**Cancer**  
Neuroendocrine tumours  
Selective internal  
radiation therapy



South Korea  
NECA

**Pregnancy**  
Postpartum haemorrhage  
Intrauterine vacuum-  
induced haemorrhage  
control



Spain  
OSTEBA

**Cardiovascular**  
Refractory angina  
Coronary sinus  
reducing stent



South Korea  
NECA

**Surgery**  
Gastric wall drainage  
Endoscopic pancreatic  
necrosectomy



England  
NICE IPG787

**Endocrine**  
Type 2 diabetes  
Endoscopic duodenal  
mucosal resurfacing



South Korea  
NECA

**Surgery**  
Biliary duct stone  
Holmium laser  
lithotripsy



### Non-pharmacological Technologies



**South Korea  
NECA**

**Surgery**  
Colorectal cancer  
surgery  
Near infrared  
indocyanine green



**Approved**



**South Korea  
NECA**

**Surgery**  
Spinal surgery  
Robot-assisted  
spinal surgery



**Approved**



**South Korea  
NECA**

**Surgery**  
Glaucoma  
Suture-assisted  
canaloplasty



**Not  
approved**



**South Korea  
NECA**

**Surgery**  
Carpal tunnel syndrome  
Thread carpal tunnel  
release using metallic  
stripper



**Not  
approved**

### Diagnostic Testing



**South Korea**  
**NECA**

**Blood**  
**Thrombosis**  
**Platelet drug**  
**response assay**



**Australia**  
**TGA**

**Cardiovascular**  
**Multiple: Heart, liver,**  
**eye**  
**Indocyanine Green**



**England**  
**NICE DG58**

**Cancer**  
**Breast cancer**  
**Tumour profiling**  
**tests**



**South Korea**  
**NECA**

**Gastrointestinal**  
**Chronic liver disease**  
**Spleen stiffness**  
**measurement**



**Ireland**  
**HIQA**

**Cardiovascular**  
**Aneurysm**  
**Abdominal screening**



**South Korea**  
**NECA**

**Infection**  
**Bacterial**  
**Polymerase chain**  
**reaction (real-time PCR)**



**England**  
**NICE DG57**

**Cardiovascular**  
**Stroke**  
**AI-derived software**



**Ireland**  
**HIQA**

**Musculoskeletal**  
**Developmental dysplasia**  
**of the hip**  
**Universal ultrasound**  
**screening**



### Diagnostic Testing



Canada  
CADTH RC1533-000

Pregnancy  
Cytomegalovirus  
Newborn Screening



### Other Guidance



**Switzerland**  
**BAG**

**Cancer**  
**Breast cancer**  
**Multigene expression**  
**tests**



**Evidence**  
**review**



**Canada**  
**CADTH CY0016-000**

**Pregnancy**  
**Cytomegalovirus**  
**Newborn Screening**



**Evidence**  
**review**



**Canada**  
**CADTH HC0087-000**

**Endocrine**  
**Diabetes**  
**Glucagon-like peptide-**  
**1 receptor agonists**



**Evidence**  
**review**



**Sweden**  
**SBU ut202411**

**Gastrointestinal**  
**Inflammatory bowel**  
**disease**  
**SNRIs**  
**SSRIs**

Selective serotonin  
reuptake inhibitors  
Serotonin-norepinephrine  
reuptake inhibitors



**Evidence**  
**review**



**Canada**  
**CADTH HC0069-000**

**Infection**  
**COVID-19**  
**Nirmatrelvir-Ritonavir**  
**and Remdesivir**



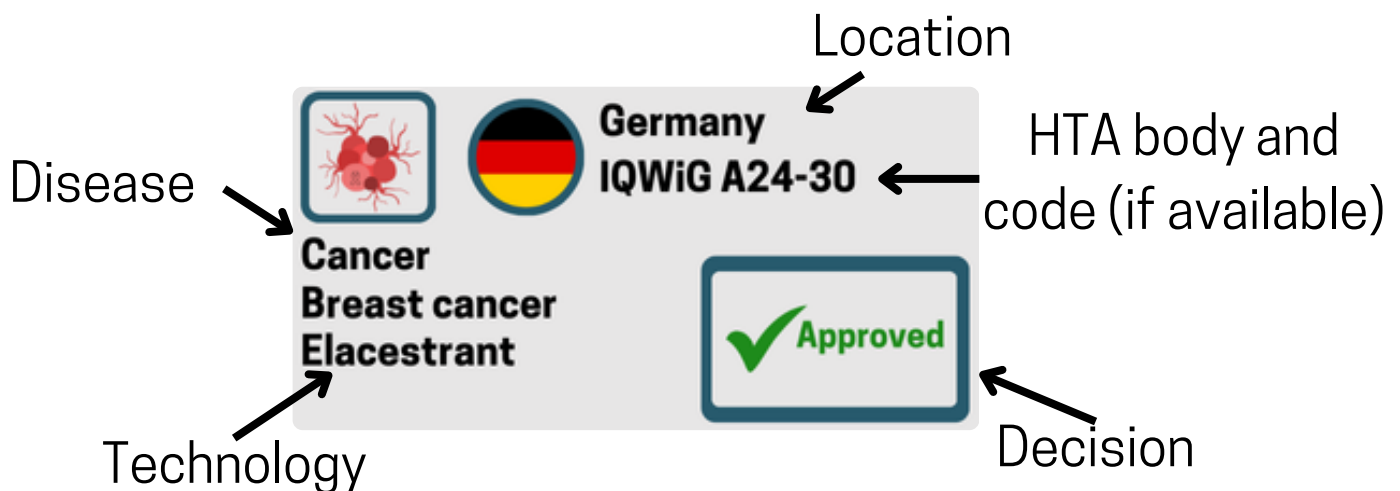
**Evidence**  
**review**

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## Further Information

HTAngel is designed to help keep you up to date with the latest HTA decisions around the world. Below is a breakdown of the tiles in the newsletter.



At Crystallise we aim to provide an innovative approach to processing information, using software tools to automate processes that are slower and less accurate when done by humans. Our approach provides clients with greater transparency and scope than they could find for the same budget elsewhere. We work with a network of experts and organisations that help us support clients efficiently and effectively, and are proud of our flexible and ingenious way of solving their problems.

For further information about HTAngel contact  
[newsletter@crystallise.com](mailto:newsletter@crystallise.com)

To speak to us about our services contact  
[contact@crystallise.com](mailto:contact@crystallise.com)