

## Issue 18: October 2024

### Almost half of submissions were approved!

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

**Good news** for: Patients with paroxysmal nocturnal haemoglobinuria, with the approval of **Danicopan** (with ravulizumab or eculizumab) in England and **Iptacopan** in Germany; **Osimertinib**, approved for non-small cell lung cancer in France and Germany; and **Dostarlimab**, approved for newly or recurrent advanced endometrial cancer in France and locally advanced dMMR/MSI-H rectal cancer in Wales.

**Mixed news** for: **Alectinib**, which was approved for non-small-cell lung cancer in France but not in Germany; **Fruquintinib**, approved for metastatic colorectal cancer in Germany and Australia but not in France; and **Pembrolizumab**, approved for non-small cell lung cancer in Scotland but not in Germany but also approved for unresectable or metastatic urothelial carcinoma in France

**Bad news** for: **Donepezil**, not approved for severe Alzheimer's disease in Brazil; **Lenvatinib**, not approved for hepatocellular carcinoma in Canada; and **Nivolumab**, not approved for unresectable or metastatic urothelial carcinoma in Germany and Scotland.

“ “  
**39 Approvals**

15 with special arrangements  
2 with orphan drug status

“ “  
**35 Not approved**  
**8 Excluded submissions**

“ “  
**3 Evidence reviews**

# HT ANGEL

Issue 18: October 2024

## Pharmacological Technologies



England  
NICE TA1010

**Blood**

Paroxysmal nocturnal  
haemoglobinuria (PNH)  
DANICOPAN WITH  
RAVULIZUMAB OR  
ECULIZUMAB



Wales  
AWTTC 4091

**Cancer**

ALK-positive NSCLC  
ALECTINIB



Germany  
IQWiG G24-16

**Blood**

Paroxysmal Nocturnal  
Hemoglobinuria (PNH)  
with hemolytic anemia  
IPTACOPAN



France  
HAS AP401

**Cancer**

Non-small cell lung  
cancer (NSCLC)  
ALECTINIB



Argentina  
IECS

**Cancer**

Prostate cancer  
177-LUTETIUM PSMA  
(TREATMENT WITH  
CABAZITAXEL)



Germany  
IQWiG A24-73

**Cancer**

Non-Small Cell Lung  
Cancer (NSCLC)  
ALECTINIB



Argentina  
IECS

**Cancer**

Prostate Cancer  
177-LUTETIUM PSMA  
(STANDARD TREATMENT)



Germany  
IQWiG A24-71

**Cancer**

Diffuse Large B-Cell  
Lymphoma and High-  
Grade B-Cell Lymphoma  
AXICABTAGENE CILOLEUCEL



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Brazil  
CONITEC

Cancer  
Chronic myeloid  
leukemia  
BOSUTINIB

Not  
approved



France  
HAS AP358

Cancer  
Newly or recurrent  
advanced endometrial  
cancer  
DOSTARLIMAB

Approved  
with special  
conditions



Scotland  
SMC 2724

Cancer  
Non-Small Cell Lung  
Cancer (NSCLC)  
CEMPIIMAB

Not  
approved



France  
HAS AP373

Cancer  
Unresectable or  
metastatic urothelial  
carcinoma  
ENFORTUMAB VEDOTIN

Approved



Canada  
CDA RC1549

Cancer  
Melanoma brain  
metastasis  
BRAF AND MEK  
INHIBITORS

Not  
approved



France  
HAS AP370

Cancer  
Metastatic colorectal  
cancer  
FRUQUINTINIB

Not  
approved



Wales  
AWTTC OW26

Cancer  
Locally advanced  
rectal cancer  
DOSTARLIMAB

Approved



Germany  
IQWiG A24-74

Cancer  
Metastatic  
Colorectal Cancer  
FRUQUINTINIB

Approved



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Australia  
PBAC

Cancer  
Metastatic  
Colorectal Cancer  
FRUQUINTINIB

✓ Approved



Canada  
CDA RC1553

Cancer  
Hepatocellular  
carcinoma  
LENVATINIB

✗ Not  
approved



Germany  
IQWiG A24-76

Cancer  
Metastatic Castration-  
Resistant Prostate  
Cancer  
GOZETOTIDE

✓ Approved  
with special  
conditions



Germany  
IQWiG A24-70

Cancer  
Unresectable or  
Metastatic Urothelial  
Carcinoma  
NIVOLUMAB

✗ Not  
approved



France  
HAS

Cancer  
Multiple myeloma  
IDECABTAGENE  
VICLEUCEL

✗ Excluded



Scotland  
SMC 2726

Cancer  
Unresectable or  
metastatic urothelial  
carcinoma  
NIVOLUMAB

✗ Not  
approved



France  
HAS AP400

Cancer  
Multiple Myeloma  
ISATUXIMAB

✗ Not  
approved



France  
HAS AP402

Cancer  
Locally advanced,  
unresectable NSCLC  
OSIMERTINIB

✓ Approved





# HT ANGEL

Issue 18: October 2024

## Pharmacological Technologies



Germany  
IQWiG A24-72

Cancer  
Non-Small Cell Lung  
Cancer (NSCLC)  
OSIMERTINIB



Scotland  
SMC 2689

Cancer  
Non-Small Cell Lung  
Carcinoma (NSCLC)  
PEMBROLIZUMAB



Germany  
IQWiG A24-46

Cancer  
Neoadjuvant+adjuvant  
NSCLC  
PEMBROLIZUMAB



France  
HAS AP381

Cancer  
Unresectable or  
metastatic urothelial  
carcinoma  
PEMBROLIZUMAB



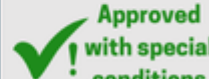
Germany  
IQWiG A24-93

Cancer  
Neoadjuvant+adjuvant  
NSCLC  
PEMBROLIZUMAB  
(Addendum)



England  
NICE TA1013

Cancer  
Acute Myeloid Leukemia  
(AML) with FLT3-ITD  
mutation  
QUIZARTINIB



Wales  
AWTTC 5213

Cancer  
Non-Small Cell Lung  
Cancer (NSCLC)  
PEMBROLIZUMAB



Scotland  
SMC 2678

Cancer  
Prostate Cancer  
RELUGOLIX



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Scotland  
SMC 2674

Cancer  
Multiple Myeloma  
SELINEXOR



Wales  
AWTTC 5363

Eye  
Neovascular (wet) age-related macular degeneration  
BEVACIZUMAB GAMMA



Wales  
AWTTC 4144

Cancer  
Ototoxicity due to cisplatin chemotherapy  
ANHYDROUS SODIUM THIOSULFATE



Scotland  
SMC 2685

Eye  
Macular oedema secondary to retinal vein occlusion  
FARICIMAB



Brazil  
CONITEC

Cancer  
NSCLC with ALK translocation  
TYROSINE KINASE INHIBITORS



England  
NICE TA1009

Eye  
Primary Open-Angle Glaucoma or Ocular Hypertension  
LATANOPROST-NETARSUDIL



Australia  
PBAC

Endocrine  
Endogenous Cushing Syndrome  
OSILODROSTAT



Canada  
CDA RC1552

Gastrointestinal  
Inflammatory Bowel Disease  
EARLY BIOLOGIC TREATMENT



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Wales  
AWTTC 4543

Gastrointestinal  
Primary Biliary  
Cholangitis (PBC)  
ELAFIBRANOR



Wales  
AWTTC 155

Genetic & Metabolic  
Mucopolysaccharidosis VI  
(Maroteaux-Lamy  
syndrome)  
GALSULFASE



France  
HAS AP396

Genetic & Metabolic  
Pompe disease  
AVALGLUCOSIDASE  
ALFA



France  
HAS AP386

Genetic & Metabolic  
Cystic fibrosis  
KAFTRIO (ivacaftor/tozacaftor  
/alexacaftor)  
in combination with  
KALYDECO (ivacaftor)



England  
NICE TA1011

Genetic & Metabolic  
Tumours associated with  
von Hippel-Lindau disease  
BELZUTIFAN



France  
HAS AP406

Genetic & Metabolic  
Progressive Familial  
Intrahepatic Cholestasis  
(PFIC)  
MARALIXIBAT



Wales  
AWTTC 5344

Genetic & Metabolic  
Hereditary  
Transthyretin-Related  
Amyloidosis  
EPLONTERSEN



France  
HAS AP369

Genetic & Metabolic  
Obesity  
SETMELANOTIDE



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Brazil  
CONITEC

**Genetic & Metabolic**  
Hereditary  
transthyretin-mediated  
amyloidosis

VUTRISIRAN SODIUM

Not  
approved



Brazil  
CONITEC

**Musculoskeletal**  
Mineral bone disorder  
in CKD

ALUMINIUM HYDROXIDE  
+ ALFACALCIDOL

Not  
approved



Brazil  
CONITEC

**Infection**

Influenza infection  
INFLUENZA VACCINE

Not  
approved



Brazil  
CONITEC

**Musculoskeletal**  
Ankylosing  
spondylitis

TOFACITINIB CITRATE

Not  
approved



Scotland  
SMC 2659

**Infection**

Invasive Candidiasis  
REZAFUNGIN  
ACETATE

Approved  
with special  
conditions



Brazil  
CONITEC

**Neurology**  
Severe Alzheimer's  
disease

DONEPEZIL

Not  
approved



Canada  
CDA RC1558

**Mental Health**

Major Depressive  
Disorder and treatment-  
resistant depression  
BUPROPION

Approved



Canada  
CDA RC1557

**Neurology**  
Epilepsy

GABAPENTIN

Approved  
with special  
conditions





# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



France  
HAS AP394

Neurology  
Amyotrophic Lateral  
Sclerosis (ALS)  
TOFERSEN

Not  
approved



Brazil  
CONITEC

Respiratory  
Severe allergic asthma  
DUPILUMAB +  
OMALIZUMAB

Not  
approved



Germany  
IQWiG G24-17

Neurology  
SOD1-associated  
Amyotrophic Lateral  
Sclerosis (ALS)  
TOFERSEN

Approved  
orphan drug  
status



Brazil  
CONITEC

Skin  
Atopic dermatitis  
METHOTREXATE

Not  
approved



Scotland  
SMC 2725

Pregnancy  
Contraception  
DROSPIRENONE

Not  
approved



Brazil  
CONITEC

Skin  
Atopic dermatitis  
MOMETASONE  
FUROATE

Not  
approved



Brazil  
CONITEC

Respiratory  
Severe eosinophilic  
asthma  
BENRALIZUMAB

Not  
approved



Wales  
AWTTC 4973

Skin  
Facial angiofibroma  
associated with TSC  
SIROLIMUS

Excluded



# HTANGEL

Issue 18: October 2024

## Pharmacological Technologies



Brazil  
CONITEC

Skin  
Atopic dermatitis  
TACROLIMUS



# HTANGEL

Issue 18: October 2024

## Non-pharmacological Technologies



Canada  
CDA RC1550

Cancer  
Ovarian Cancer  
BILATERAL  
OPPORTUNISTIC  
SALPINGECTOMY

Not  
approved



Norway  
NIPH

Cancer  
Endometrial Cancer and  
Benign Gynecological  
Conditions  
ROBOT-ASSISTED  
HYSTERECTOMY

Not  
approved



Norway  
NIPH

Cancer  
Prostate cancer  
ROBOT-ASSISTED  
PROSTATECTOMY

Approved  
with special  
conditions



Norway  
NIPH

Cancer  
Rectal cancer  
ROBOT-ASSISTED  
RECTAL RESECTION

Not  
approved



South Korea  
NECA HTA-2024-36

Cardiovascular  
Atrial Fibrillation  
PULSED FIELD  
ABLATION

Approved



South Korea  
NECA PV-2023-10

Cardiovascular  
Ischemic Heart Disease  
REMOTE CATHETER  
CONTROL ROBOT SYSTEM

Approved



Norway  
NIPH

Genitourinary  
Benign gynecological  
conditions  
ROBOT-ASSISTED  
HYSTERECTOMY FOR BENIGN  
CONDITIONS

Not  
approved



South Korea  
NECA HTA-2024-38

Musculoskeletal  
Partial medial meniscus  
defects  
COLLAGEN MENISCUS  
IMPLANT

Not  
approved



# HTANGEL

Issue 18: October 2024

## Non-pharmacological Technologies



Argentina  
IECS

### Surgery

Transfemoral amputation  
OSSEOINTEGRABLE  
PROSTHESES (INTOLERANCE  
TO SOCKET CONE)



Argentina  
IECS

### Surgery

Transfemoral amputation  
OSSEOINTEGRABLE  
PROSTHESES (TOLERANCE TO  
SOCKET CONE)





# HTANGEL

Issue 18: October 2024

## Diagnostic Testing



England  
NICE DG61

Cardiovascular  
Heart failure  
HEART FAILURE  
ALGORITHMS

✓ Approved  
with special  
conditions



South Korea  
NECA RR-2024-3

Musculoskeletal  
Sarcopenia  
SHORT PHYSICAL  
PERFORMANCE BATTERY

✓ Approved



Brazil  
CONITEC

Genetic & Metabolic  
Exocrine Pancreatic  
Insufficiency  
ENDOSCOPIC  
ULTRASOUND

✗ Not  
approved



South Korea  
NECA HTA-2024-39

Musculoskeletal  
Foot, Ankle, and Knee  
Conditions  
WEIGHT BEARING CONE BEAM  
COMPUTED TOMOGRAPHY

✓ Approved



Brazil  
CONITEC

Infection  
Meningitis and  
Encephalitis  
PCR MULTIPLEX RAPID  
TEST

✓ Approved  
with special  
conditions



South Korea  
NECA HTA-2024-40

Neurology  
Delirium  
CONFUSION  
ASSESSMENT METHOD

✓ Approved  
with special  
conditions



Brazil  
CONITEC

Genetic & Metabolic  
Exocrine Pancreatic  
Insufficiency  
FECAL ELASTASE TEST

✗ Not  
approved



# HTANGEL

Issue 18: October 2024

## Other Guidance



**Australia  
PBAC**

**Infection**

**Hepatitis C Infection  
HEPATITIS C  
MEDICINES**



**Ireland  
HIQA**

**Infection**

**Influenza infection  
ENHANCED INACTIVATED  
INFLUENZA VACCINES**



**Australia  
PBAC**

**Other**

**Pain Management  
OPIOIDS (MULTIPLE)**

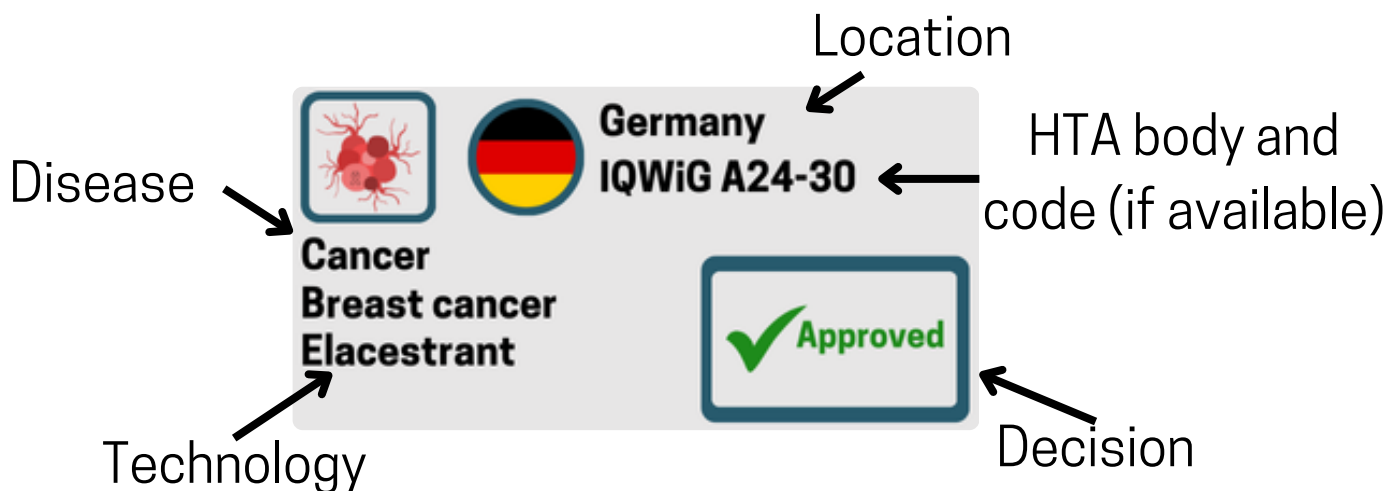


# HTANGEL

Issue 18: October 2024

## 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)

