

## Issue 33: January 2026

### Greater number of approval in January compared to non-approvals!

This newsletter summarises final decisions from HTA bodies around the world from published reports in January 2026.

**Good news** for: **Durvalumab**, approved for small-cell lung cancer and muscle-invasive urothelial cancer in Germany; **Nirogacestat**, approved for desmoid tumours in France and Germany; and **Nivolumab**, approved for colorectal cancer in Scotland and excluded from assessment for non-small-cell lung cancer in Wales.

**Mixed news** for: **Dupilumab**, approved for severe atopic dermatitis and asthma in South Korea but not approved for urticaria in Scotland and excluded in Wales; and **Pembrolizumab**, approved for pan-cancer in Australia but terminated submission for mesothelioma in England.

**Bad news** for: **Concizumab**, not approved or terminated submission for haemophilia A and B in Germany and England; **Depemokimab**, with terminated submission for rhinosinusitis in England and excluded in Wales; and **Tislelizumab**, not approved for small-cell and non-small-cell lung cancer and nasopharyngeal carcinoma in Germany.

“

**49 Approvals**

20 with special arrangements  
3 with orphan drug status

“

**24 Not approved**

**7 Excluded**

**5 Terminated**

“

**9 Evidence reviews**

# HT ANGEL

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## Pharmacological Technologies



Germany  
IQWiG A25-141

Blood  
Haemorrhage  
ANDEXANET ALFA

Not approved



Wales  
AWTTC 8041

Blood  
Haemophilia A,  
Haemophilia B  
CONCIZUMAB

Excluded



England  
NICE TA1124

Blood  
Haemophilia A,  
Haemophilia B  
CONCIZUMAB

Terminated



Scotland  
SMC2852

Blood  
Sickle cell disease  
EXAGAMGLOGENE  
AUTOTEMCEL

Approved



Germany  
IQWiG A25-123

Blood  
Haemophilia  
CONCIZUMAB

Not approved



Scotland  
SMC2759

Blood  
Haemophilia A,  
Haemophilia B  
MARSTACIMAB

Approved with special conditions



Germany  
IQWiG A25-124

Blood  
Haemophilia  
CONCIZUMAB

Not approved



South Korea  
HIRA-2025-224

Blood, Neurology  
Paroxysmal nocturnal  
hemoglobinuria, Atypical  
hemolytic uremic syndrome,  
Neuromyelitis optica  
spectrum disorder  
ECULIZUMAB

Approved with special conditions



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## Pharmacological Technologies



**South Korea**  
HIRA-2025-224

Blood, Neurology, Musculoskeletal  
Paroxysmal nocturnal  
hemoglobinuria, Atypical hemolytic  
uremic syndrome, Neuromyelitis  
optica spectrum disorder generalized  
myasthenia gravis  
RAVULIZUMAB



**France**  
HAS AP549

**Cancer**  
Haematological  
malignancies  
DOROCUBICEL, NON-  
EXPANDED CD34-NEGATIVE  
CELLS



**England**  
NICE TA1122

**Cancer**  
Lung cancer  
AMIVANTAMAB,  
LAZERTINIB



**Germany**  
IQWiG A25-96

**Cancer**  
Lung cancer  
DURVALUMAB



**England**  
NICE TA1120

**Cancer**  
Renal cancer  
AVELUMAB, AXITINIB



**Germany**  
IQWiG A25-97

**Cancer**  
Bladder cancer  
DURVALUMAB



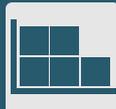
**Scotland**  
SMC2895

**Cancer**  
Multiple myeloma  
DARATUMUMAB



**England**  
NICE TA1118

**Cancer**  
Solid tumours  
ENTRECTINIB



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## Pharmacological Technologies



Brazil  
Conitec

Cancer  
Multiple myeloma  
LENALIDOMIDE

Not approved



Germany  
IQWiG G25-29

Cancer  
Desmoid tumour  
NIROGACESTAT

Approved orphan drug status



Germany  
IQWiG A25-127

Cancer  
Multiple myeloma  
LIVOSELTAMAB

Not approved



Scotland  
SMC2820

Cancer  
Colorectal cancer  
NIVOLUMAB

Approved



France  
HAS AP532

Cancer  
Prostate cancer  
NIRAPARIBACETATE D  
ABIRATERONE

Not approved



Wales  
AWTTC 4999

Cancer  
Lung cancer  
NIVOLUMAB

Excluded



France  
HAS AP555

Cancer  
Desmoid tumours  
NIROGACESTAT

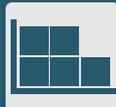
Approved



England  
NICE TA1125

Cancer  
Mesothelioma  
PEMBROLIZUMAB

Terminated



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## Pharmacological Technologies



Australia  
PBAC

Cancer  
Cancer  
PEMBROLIZUMAB

Approved



Scotland  
SMC2840

Cancer  
Lung cancer  
SERPLULIMAB

Not approved



Wales  
AWTTC 5002

Cancer  
Mesothelioma  
PEMBROLIZUMAB

Excluded



Germany  
IQWiG A25-118

Cancer  
Lung cancer  
TISLELIZUMAB

Not approved



Brazil  
Conitec

Cancer  
Breast cancer  
PERTUZUMAB,  
TRASTUZUMAB

Not approved



Germany  
IQWiG A25-122

Cancer  
Lung cancer  
TISLELIZUMAB

Not approved



Scotland  
SMC2897

Cancer  
Mantle cell  
lymphoma  
PIRTOBRUTINIB

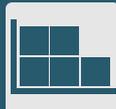
Not approved



Germany  
IQWiG A25-119

Cancer  
Nasopharyngeal  
carcinoma  
TISLELIZUMAB

Not approved



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## Pharmacological Technologies



Germany  
IQWiG A25-128

Cancer  
Stomach cancer  
TRASTUZUMAB  
DERUXTECAN

✓ Approved



England  
NICE TA1119

Cancer  
Chronic lymphocytic  
leukaemia  
VENETOCLAX,  
OBINUTUZUMAB

✓ Approved  
with special  
conditions



France  
HAS AP550

Cancer  
Astrocytoma,  
Oligodendroglioma  
VORASIDENIB

✓ Approved



Scotland  
SMC2839

Cancer  
Gastric cancer,  
Gastroesophageal junction  
cancer  
ZOLBETUXIMAB

✓ Approved



Australia  
PBAC

Cardiovascular  
Heart failure  
EPLERENONE

✓ Approved



South Korea  
HIRA 2025-224

Cardiovascular  
Chronic arterial  
occlusive disease  
CILOSTAZOL,  
ROSUVASTATIN

✓ Approved



Brazil  
Conitec

Endocrine  
Hypogonadotropic  
hypogonadism  
ESTRADIOL TRANSDERMAL  
PATCH

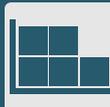
✗ Not  
approved



Brazil  
Conitec

Endocrine  
Hypogonadotropic  
hypogonadism  
TESTOSTERONE INJECTION

✗ Not  
approved



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## Pharmacological Technologies



**Brazil**  
Conitec

**Endocrine**  
**Hypogonadotropic hypogonadism**  
**TESTOSTERONE INJECTION**

**Not approved**



**France**  
HAS AP547

**Genetic & Metabolic**  
**Aromatic L-amino acid decarboxylase deficiency**  
**ELADOCAGENE**  
**EXUPARVOVEC**

**Approved**



**Scotland**  
SMC2873

**Eye**  
**Dry Eye Disease**  
**CICLOSPORIN**

**Approved with special conditions**



**South Korea**  
HIRA 2025-224

**Genetic & Metabolic**  
**Diabetes mellitus**  
**GLUCAGON**

**Approved with special conditions**



**England**  
NICE TA1121

**Genetic & Metabolic**  
**Transthyretin amyloidosis**  
**ACORAMIDIS**

**Approved with special conditions**



**South Korea**  
HIRA 2025-224

**Genetic & Metabolic**  
**Alagille syndrome**  
**MARALIXIBAT**

**Approved with special conditions**



**Wales**  
AWTTC 4848

**Genetic & Metabolic**  
**Transthyretin-related amyloidosis cardiomyopathy**  
**ACORAMIDIS**

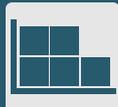
**Excluded**



**Germany**  
IQWiG G25-30

**Genetic & Metabolic**  
**Hereditary angioedema**  
**SEBETRALSTAT**

**Approved orphan drug status**



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## Pharmacological Technologies



Germany  
IQWiG G25-23

Genetic & Metabolic  
Phenylketonuria  
SEPIAPTERIN



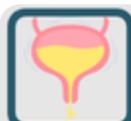
Germany  
IQWiG A25-149

Genetic & Metabolic  
Transthyretin  
amyloidosis  
VUTRISIRAN



France  
HAS AP517

Genetic & Metabolic  
Obesity  
SETMELANOTIDE



Wales  
AWTTC 4836

Genitourinary  
Lupus nephritis  
OBINUTUZUMAB



Australia  
PBAC

Genetic & Metabolic  
Alpha-mannosidosis  
VELMANASE ALFA



South Korea  
HIRA-2025-224

Infection  
Bacterial infection  
LEVOFLOXACIN



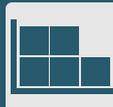
Germany  
IQWiG A25-93

Genetic & Metabolic  
Transthyretin  
amyloidosis  
VUTRISIRAN



Australia  
PBAC

Infection  
COVID-19  
RAXTOZINAMERAN



Crystallise

# HTANGEL

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## Pharmacological Technologies



Australia  
PBAC

Infection

Respiratory syncytial  
virus infection  
RSVPREF30A



England  
NICE TA1126

Neurology

Multiple sclerosis  
NATALIZUMAB



Australia  
PBAC

Gastrointestinal

Primary biliary  
cholangitis  
SELADELPAR



Australia  
PBAC

Neurology

Spinal muscular  
atrophy  
NUSINERSEN



Australia  
PBAC

Musculoskeletal

Rheumatoid arthritis  
HYDROXYCHLOROQUINE



South Korea  
HIRA 2025-224

Respiratory

Eosinophilic asthma  
BENRALIZUMAB



Canada  
CDA RC1587-000

Neurology

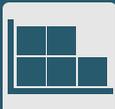
Limb spasticity, Cervical  
dystonia  
BOTULINUM TOXIN  
A PRODUCTS



France  
HAS AP539

Respiratory

Bronchiectasis  
BRENSOCATIB



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## Pharmacological Technologies



England  
NICE TA1123

Respiratory  
Chronic  
rhinosinusitis  
DEPEMOKIMAB



South Korea  
HIRA 2025-224

Respiratory  
Asthma  
OMALIZUMAB



Wales  
AWTTC 7040

Respiratory  
Rhinosinitis, Nasal  
polyps  
DEPEMOKIMAB



South Korea  
HIRA 2025-224

Respiratory  
Eosinophilic asthma  
RESLIZUMAB



South Korea  
HIRA 2025-224

Respiratory  
Eosinophilic asthma  
MEPOLIZUMAB



South Korea  
HIRA 2025-224

Respiratory, Skin  
Asthma, Atopic  
dermatitis  
DUPILUMAB



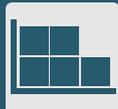
France  
HAS AP570

Respiratory  
Interstitial lung  
disease  
NINTEDANIB



Germany  
IQWiG A25-121

Musculoskeletal  
Enthesitis-related  
arthritis  
IXEKIZUMAB



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## Pharmacological Technologies



Scotland  
SMC2896

Skin  
Urticaria  
DUPILUMAB

 Not  
approved



Wales  
AWTTC 5072

Skin  
Atopic dermatitis  
DUPILUMAB

 Excluded



England  
NICE TA972

Skin  
Facial angiofibroma  
SIROLIMUS

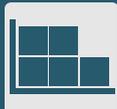
 Terminated



Scotland  
SMC2894

Skin  
Acne vulgaris  
CLASCOTERONE

 Not  
approved



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## Non-pharmacological Technologies



South Korea  
NECA HTA-2026-1

**Cancer**

Lung cancer  
AUGMENTED FLUOROSCOPY  
AND SYNTHETIC  
TOMOGRAPHY IMAGING-  
BASED GUIDED  
BRONCHOSCOPY

Approved



England  
NICE HTG766

**Musculoskeletal  
Osteoarthritis  
DIGITAL  
TECHNOLOGIES**

Approved  
with special  
conditions



England  
NICE IPG811, HTG767

**Gastrointestinal  
Barrett's oesophagus  
BALLOON  
CRYOABLATION**

Not  
approved



South Korea  
NECA RR-2026-1

**Respiratory  
Obstructive sleep  
apnoea  
MAXILLOMANDIBULAR  
ADVANCEMENT**

Approved



South Korea  
Innovation-2025-12

**Mental Health  
ADHD  
COGNITIVE  
MULTITASKING TRAINING**

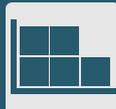
Approved  
with special  
conditions



England  
NICE HTG768

**Mental Health  
Eating disorders  
DIGITAL SELF HELP**

Approved  
with special  
conditions



### Diagnostic Testing



**South Korea**  
**NECA RR-2026-3**

#### **Cancer**

**Anal intraepithelial  
neoplasia**

**ANAL LIQUID  
CYTOPATHOLOGY TEST**



**South Korea**  
**NECA RR-2026-1**

#### **Mental Health**

**Psychosocial disorder,  
Behavioural disorder  
TEMPOROMANDIBULAR  
DISORDERS AXIS II  
COMPREHENSIVE TEST**



**South Korea**  
**NECA HTA-2025-33**

#### **Other Pain**

**SURGICAL PLETH  
INDEX MONITORING**



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## Other Guidance



Germany  
IQWiG G25-39

Cancer  
Lung cancer  
DURVALUMAB



United States  
AHRQ-Kidney-  
Stones-2026

Genitourinary  
Kidney stones  
NR



Germany  
IQWiG A25-151

Cancer  
Bladder cancer  
DURVALUMAB



Canada  
CDA RD0076-000 -  
RE0052-000

Infectious disease  
Influenza  
ANTIVIRAL DRUGS



Germany  
IQWiG G25-37

Genetic & Metabolic  
Phenylketonuria  
SEPIAPTERIN



United States  
AHRQ-Child-Growth-  
Development-2026

Mental Health  
Child development  
NR



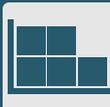
Canada  
CDA HC0109-000

Blood  
Immune  
thrombocytopenia  
ELTROMBOPAG,  
ROMIPLOSTIM



Canada  
CDA HC0108-000

Other  
Drug toxicity  
DRUG-CHECKING  
TECHNOLOGIES



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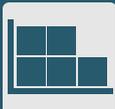
## Other Guidance



Canada

CDA HC0086-000

Respiratory  
COPD  
LONG-ACTING  
INHALABLE DRUGS

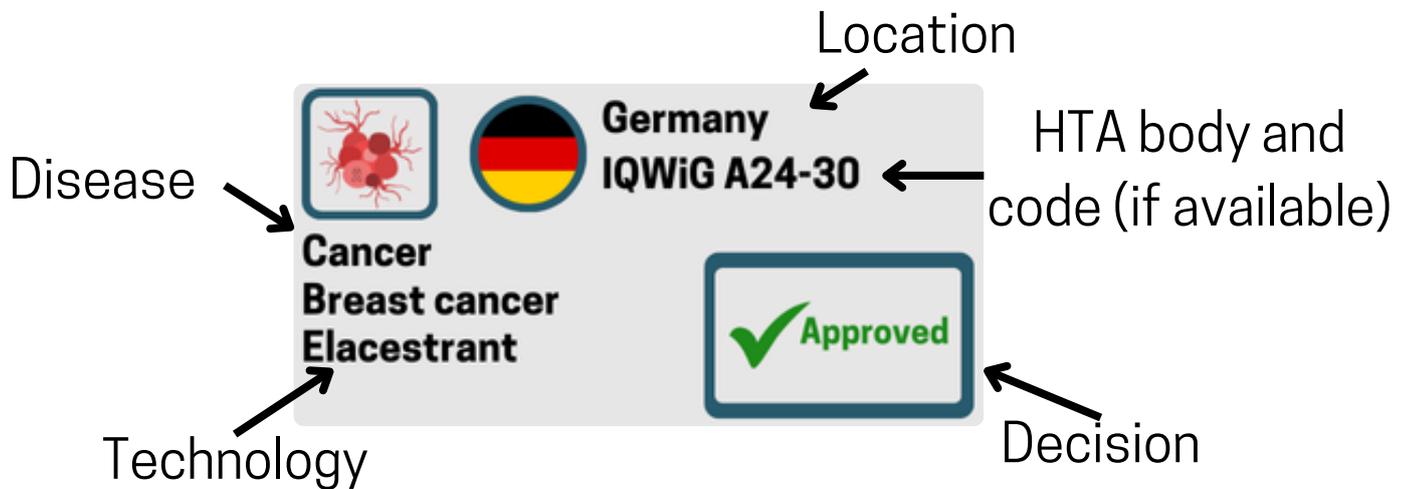


# HTANGEL

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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)

