

# HTANGEL

KEEPING YOU UP-TO-DATE ON  
INTERNATIONAL HTA DECISIONS

## Issue 32: December 2025

**Immuno-oncology agents led December HTA decisions, featuring significant approvals and key rejections due to ongoing evidence challenges.**

This newsletter summarises final decisions from HTA bodies around the world from published reports in December 2025.

**Good news** for: **Delgocitinib**, approved for hand eczema in Scotland;  
**Pembrolizumab**, approved for cervical, gastric and urothelial cancers in France;  
and **Vutrisiran**, approved for transthyretin amyloidosis with cardiomyopathy in England.

**Mixed news** for: **Givinostat**, approved for Duchenne muscular dystrophy in Scotland but not in France.

**Bad news** for: **Acalabrutinib**, not approved for mantle cell lymphoma or chronic lymphocytic leukaemia in Germany; **Dapagliflozin**, not approved for heart failure in Brazil; and **Nivolumab**, not approved for oesophageal or colorectal cancer in Germany.

“

**39 Approvals**

6 with special arrangements  
1 with orphan drug status

“

**28 Not approved**

**6 Excluded submissions**

### Pharmacological Technologies



**Brazil**  
**CONITEC**

**Blood**  
**Beta-thalassaemia,**  
**Anaemia**  
**LUSPATERCEPT**



**Brazil**  
**CONITEC**

**Blood**  
**Haemophilia A**  
**EMICIZUMAB**



**France**  
**HAS AP524**

**Blood**  
**Haemophilia B**  
**CONCIZUMAB**



**England**  
**NICE TA1116**

**Cancer**  
**Acute lymphoblastic**  
**leukaemia**  
**OBECABTAGENE**  
**AUTOLEUCEL**



**Wales**  
**AWTTC OW32**

**Cancer**  
**Acute myeloid**  
**leukaemia**  
**VENETOCLAX**



**England**  
**NICE TA1113**

**Cancer**  
**B-cell lymphoma**  
**GLOFITAMAB**



**France**  
**HAS AP534**

**Cancer**  
**Biliary tract cancer**  
**ZANIDATAMAB**



**France**  
**HAS AP529**

**Cancer**  
**Breast cancer**  
**INAVOLISIB**



### Pharmacological Technologies



Scotland  
SMC2288

Cancer  
Breast cancer  
TRASTUZUMAB  
DERUXTECAN

Not approved



Germany  
IQWiG A25-85

Cancer  
Chronic lymphocytic  
leukaemia  
ACALABRUTINIB

Not approved



France  
HAS AP440

Cancer  
Cervical cancer  
PEMBROLIZUMAB

Approved



Brazil  
CONITEC

Cancer  
Chronic myeloid  
leukaemia  
ASCIMINIB

Approved



Germany  
IQWiG A25-112

Cancer  
Cervical cancer  
TISOTUMAB VEDOTIN

Not approved



Germany  
IQWiG A25-135

Cancer  
Colorectal cancer  
NIVOLUMAB

Not approved



Germany  
IQWiG A25-91

Cancer  
Chronic lymphocytic  
leukaemia  
ACALABRUTINIB

Not approved



Germany  
IQWiG A25-80

Cancer  
Colorectal cancer  
NIVOLUMAB

Not approved

### Pharmacological Technologies



England  
NICE TA1117

Cancer  
Endometrial cancer  
DOSTARLIMAB



France  
HAS AP443

Cancer  
Gastric cancer,  
Gastroesophageal junction  
cancer  
PEMBROLIZUMAB



Scotland  
SMC2878

Cancer  
Lung cancer  
AMIVANTAMAB



Wales  
AWTTC 5305,  
AWTTC 7960

Cancer  
Lung cancer  
AMIVANTAMAB



France  
HAS AP533

Cancer  
Lung cancer  
DURVALUMAB



Germany  
IQWiG A25-143

Cancer  
Mantle cell  
lymphoma  
ACALABRUTINIB



Germany  
IQWiG A25-89

Cancer  
Mantle cell  
lymphoma  
ACALABRUTINIB



France  
HAS AP521

Cancer  
Mantle cell  
lymphoma  
IBRUTINIB



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## Pharmacological Technologies



**Wales**

AWTTC 5157, AWTTC  
7980, AWTTC 7981

**Cancer**

**Multiple myeloma**  
**BELANTAMAB**  
**MAFODOTIN**



**Excluded**



**Wales**

AWTTC 3880,  
AWTTC 7962

**Cancer**

**Prostate cancer**  
**TALAZOPARIB**



**Excluded**



**England**

NICE TA1114

**Cancer**

**Multiple myeloma**  
**TALQUETAMAB**



**Approved**  
with special  
conditions



**France**

HAS AP381

**Cancer**

**Urothelial cancer**  
**PEMBROLIZUMAB**



**Approved**



**Germany**

IQWiG A25-142

**Cancer**

**Oesophageal cancer,**  
**Gastroesophageal junction**  
**cancer**  
**NIVOLUMAB**



**Not**  
**approved**



**Brazil**

CONITEC

**Cardiovascular**

**Cardiovascular risk**  
**EZETIMIBE**



**Not**  
**approved**



**Germany**

IQWiG A25-88

**Cancer**

**Oesophageal cancer,**  
**Gastroesophageal junction**  
**cancer**  
**NIVOLUMAB**



**Not**  
**approved**



**Brazil**

CONITEC

**Cardiovascular**

**Cardiovascular risk**  
**ROSUVASTATIN**



**Not**  
**approved**

### Pharmacological Technologies



**Brazil**  
**CONITEC**

**Cardiovascular**  
**Heart failure**  
**DAPAGLIFLOZIN**



**Not**  
**approved**



**France**  
**HAS AP526**

**Eye**  
**Graves'**  
**ophthalmopathy**  
**TEPROTUMUMAB**



**Approved**



**Germany**  
**IQWiG A25-114**

**Cardiovascular**  
**Polyangiitis, Eosinophilic**  
**granulomatosis**  
**AVACOPAN**



**Not**  
**approved**



**South Korea**  
**HIQA 2025-189**

**Gastrointestinal**  
**Gastroesophageal**  
**reflux disease**  
**FEXUPRAZAN**



**Approved**



**England**  
**NICE TA1115**

**Cardiovascular, Genetic**  
**& Metabolic**  
**Cardiomyopathy,**  
**Amyloidosis**  
**VUTRISIRAN**



**Approved**  
**with special**  
**conditions**



**Germany**  
**IQWiG A25-117**

**Gastrointestinal**  
**Liver fibrosis, Metabolic**  
**dysfunction-associated**  
**steatohepatitis**  
**RESMETIROME**



**Not**  
**approved**



**South Korea**  
**HIQA 2025-189**

**Endocrine**  
**Cushing syndrome**  
**OSILODROSTAT**



**Approved**



**South Korea**  
**HIQA 2025-189**

**Gastrointestinal,**  
**Musculoskeletal, Skin**  
**Multiple conditions -**  
**see page for details**  
**INFLIXIMAB**



**Approved**

### Pharmacological Technologies



Scotland  
SMC2836

Genetic & Metabolic  
Activated PI3K-delta  
(APDS) syndrome  
LENIOLISIB



France  
HAS AP531

Genetic & Metabolic  
Obesity, Bardet  
Biedl syndrome  
SETMELANOTIDE



Scotland  
SMC2806

Genetic & Metabolic  
Alagille syndrome  
MARALIXIBAT



Brazil  
CONITEC

Genitourinary  
Uterine leiomyoma  
LEVONORGESTREL-  
RELEASING IUD



France  
HAS AP530

Genetic & Metabolic  
Duchenne muscular  
dystrophy  
GIVINOSTAT



Brazil  
CONITEC

Genitourinary, Endocrine  
Chronic kidney disease,  
Type 2 diabetes mellitus  
FINERENONE



Scotland  
SMC2856

Genetic & Metabolic  
Duchenne muscular  
dystrophy  
GIVINOSTAT



Brazil  
CONITEC

Infection  
Hepatitis C  
ELBASVIR/GRAZOPREVR AND  
LEDIPASVIR/SOFOSBUVIR



### Pharmacological Technologies



**Brazil  
CONITEC**

**Infection  
Hepatitis C  
SOFOSBUVIR/  
VELPATASVIR**

 **Approved**



**Brazil  
CONITEC**

**Infection  
Pneumococcal infection  
20-VALENT PNEUMOCOCCAL  
CONJUGATE VACCINE**

 **Approved**



**Germany  
IQWiG A25-113**

**Infection  
Hepatitis D  
BULEVIRTIDE**

 **Not  
approved**



**Brazil  
CONITEC**

**Infection  
Pneumococcal infection  
PNEUMOCOCCAL  
CONJUGATE VACCINES**

 **Approved**



**Brazil  
CONITEC**

**Infection  
Herpes zoster  
RECOMBINANT  
ADJUVANTED VACCINE**

 **Not  
approved**



**Brazil  
CONITEC**

**Infection  
Sexually transmitted  
infection  
DOXYCYCLINE**

 **Not  
approved**



**Brazil  
CONITEC**

**Infection  
Pneumococcal infection  
15-VALENT PNEUMOCOCCAL  
CONJUGATE VACCINE**

 **Approved**



**South Korea  
HIQA 2025-189**

**Musculoskeletal,  
Gastrointestinal, Skin, Eye  
Multiple conditions -  
see page for details  
ADALIMUMAB**

 **Approved**

### Pharmacological Technologies



Germany  
IQWiG A25-111

Neurology  
Alzheimer's disease  
LECANEMAB



Brazil  
CONITEC

Neurology  
Spinal muscular  
atrophy  
NUSINERSEN



South Korea  
HIQA 2025-189

Neurology  
Ataxia  
TALTIRELIN HYDRATE



Brazil  
CONITEC

Neurology  
Spinal muscular atrophy  
ONASEMNOGENE  
ABEPARVOVEC



Wales  
AWTTC 8080,  
AWTTC 5199

Neurology  
Multiple sclerosis  
NATALIZUMAB



Brazil  
CONITEC

Neurology, Endocrine  
Parkinson's disease,  
Hyperprolactinemia  
BROMOCRIPTINE  
MESYLATE



France  
HAS AP535

Neurology  
Neurofibroma  
MIRDAMETINIB



France  
HAS AP528

Other  
Poisoning  
F(AB')<sub>2</sub> FRAGMENTS OF  
EQUINE ANTI-RICIN  
IMMUNOGLOBULIN



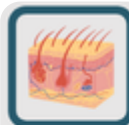
### Pharmacological Technologies



**Brazil  
CONITEC**

**Other  
Poisoning**

MESO-2,3-  
DIMERCAPTOSUCCINIC ACID



**Brazil  
CONITEC**

**Skin  
Tungiasis  
DIMETHICONE**



**Scotland  
SMC2869**

**Pregnancy  
Miscarriage  
PROGESTERONE**



**Scotland  
SMC2889**

**Renal  
Complement 3  
glomerulopathy  
IPTACOPAN**



**Scotland  
SMC2817**

**Skin  
Eczema  
DELGOCITINIB**



**South Korea  
HIQA 2025-189**

**Skin, Musculoskeletal  
Multiple conditions -  
see page for details  
SECUKINUMAB**



### Non-pharmacological Technologies



Germany  
IQWiG N24-03

Genitourinary  
Erectile dysfunction  
RADIOFREQUENCY  
ENERGY

 Not  
approved



England  
NICE IPG810/HG762

Cardiovascular  
Cardiogenic shock  
VENOARTERIAL  
EXTRACORPOREAL  
MEMBRANE OXYGENATION

 Approved

### Diagnostic Testing



**South Korea**  
**NECA HTA-2025-31**

**Cancer**

**Lung cancer**

**ELECTROMAGNETIC-GUIDED  
ROBOTIC-ASSISTED  
BRONCHOSCOPY**

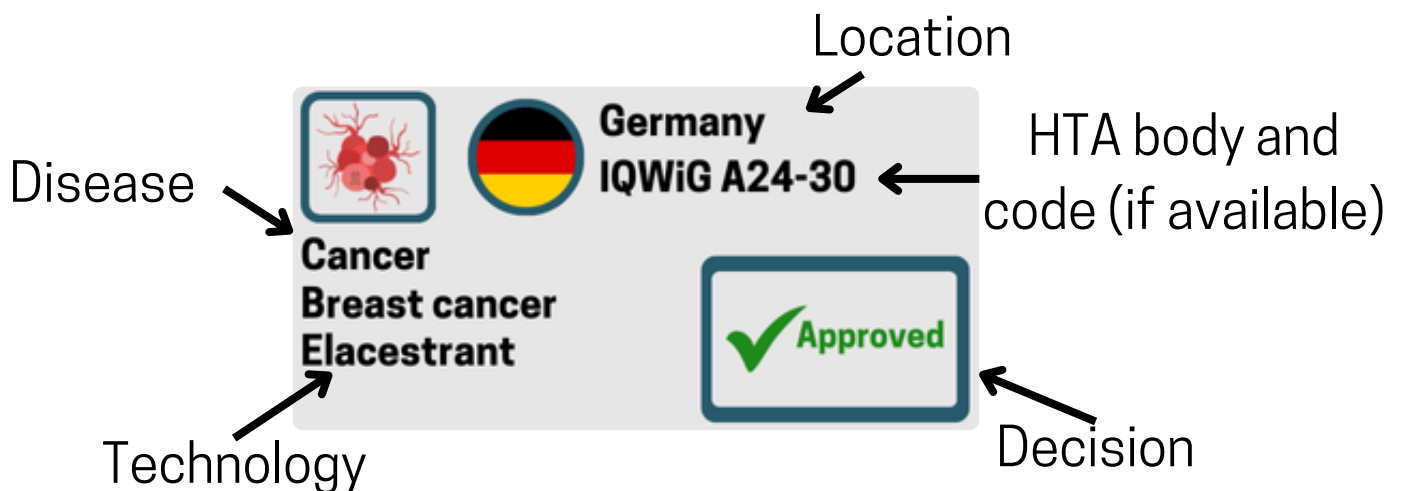


# HTANGEL

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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.



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