

Issue 30: October 2025

More than half of all the October decisions were not approved!

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

Good news for: **Bimekizumab**, approved with special conditions for hidradenitis suppurativa, axial spondyloarthritis and ankylosing spondylitis in Ireland; **Beremagene geperpavec**, approved for dystrophic epidermolysis bullosa in France; and **Odevixibat**, approved for progressive familial intrahepatic cholestasis in South Korea.

Mixed news for: **Durvalumab**, approved for small-cell lung cancer in England with special conditions and for endometrial cancer in Scotland but not approved for non-small-cell lung cancer in France.

Bad news for: **Acalabrutinib**, not approved for chronic lymphocytic leukaemia or mantle cell lymphoma in Germany; **Clascoterone**, with a terminated submission for acne vulgaris in England and no submission in Wales; **Iptacopan**, not approved for paroxymal nocturnal haemoglobinuria in Brazil or complement 3 glomerulopathy in France, with terminated submission in England and Wales; and **Nivolumab**, not approved for oesophageal cancer in Germany or non-small-cell lung cancer in Scotland

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29 Approvals

10 with special arrangements
2 with orphan drug status

“

30 Not approved
10 Excluded
4 Terminated

Pharmacological Technologies



Brazil
CONITEC

Blood
Beta-thalassaemia,
Anaemia
LUSPATERCEPT



Excluded



Brazil
CONITEC

Cancer
Breast cancer
ABEMACICLIB



Approved



Germany
IQWiG A25-56

Blood
Haemophilia B
CONCIZUMAB



Not
approved



Scotland
SMC2823

Cancer
Breast cancer
CAPIVASERTIB



Not
approved



Germany
IQWiG A25-115

Blood
Haemophilia B
CONCIZUMAB



Not
approved



Brazil
CONITEC

Cancer
Breast cancer
PERTUZUMAB



Not
approved



Brazil
CONITEC

Blood
Paroxysmal nocturnal
haemoglobinuria
IPTACOPAN



Not
approved



Germany
IQWiG A25-116

Cancer
Breast cancer
TRASTUZUMAB
DERUXTECAN



Not
approved

Pharmacological Technologies



Germany
IQWiG A25-54

Cancer
Breast cancer
TRASTUZUMAB
DERUXTECAN

Not
approved



Ireland
HSE 23056

Cancer
Gastric cancer,
Gastroesophageal junction
cancer
PEMBROLIZUMAB

Not
approved



Germany
IQWiG A25-85

Cancer
Chronic lymphocytic
leukaemia
ACALABRUTINIB

Not
approved



Brazil
CONITEC

Cancer
Lung cancer
CRIZOTINIB

Not
approved



Scotland
SMC2858

Cancer
Colorectal cancer
FRUQUINTINIB

Approved



England
NICE TA1099

Cancer
Lung cancer
DURVALUMAB

Approved
with special
conditions



Scotland
SMC2797

Cancer
Endometrial cancer
DURVALUMAB

Approved



France
HAS AP513

Cancer
Lung cancer
DURVALUMAB

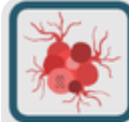
Not
approved

Pharmacological Technologies



England
NICE TA1103

Cancer
Lung cancer
LORLATINIB



Germany
IQWiG A25-89

Cancer
Lymphoma
ACALABRUTINIB



Wales
AWTTC 4494

Cancer
Lung cancer
LORLATINIB



Wales
AWTTC 5176

Cancer
Lymphoma
GLOFITAMAB



Scotland
SMC2874

Cancer
Lung cancer
NIVOLUMAB



Ireland
HSE 23023

Cancer
Lymphoma
MOSUNETUZUMAB



Germany
IQWiG A25-90

Cancer
Lymphoma
ACALABRUTINIB



Scotland
SMC2727

Cancer
Multiple myeloma
BELANTAMAB
MAFODOTIN



Pharmacological Technologies



Scotland
SMC2747

Cancer
Multiple myeloma
BELANTAMAB
MAFODOTIN



Wales
AWTTC 5210

Cancer
Multiple myeloma
TALQUETAMAB



Germany
IQWiG A25-88

Cancer
Oesophageal cancer,
Gastroesophageal junction
cancer
NIVOLUMAB



Wales
AWTTC 6680

Cancer
Prostate cancer
DAROLUTAMIDE



Germany
IQWiG A25-71

Cancer
Thyroid cancer
SELPERCATINIB



Brazil
CONITEC

Cardiovascular
Cardiovascular
assessment
EZETIMIBE



Brazil
CONITEC

Cardiovascular
Cardiovascular
assessment
ROSUVASTATIN



England
NICE TA1101

Cardiovascular
Hereditary
angioedema
GARADACIMAB



Pharmacological Technologies



Korea
HIRA 2025-169

Gastrointestinal
Cholestasis familial
progressive
ODEVIXIBAT



Approved



Brazil
CONITEC

Gastrointestinal
Crohn's disease
USTEKINUMAB



Approved



Germany
IQWiG A25-93

Genetic & Metabolic
Amyloidosis
VUTRISIRAN



Not
approved



Korea
HIRA 2025-169

Genetic & Metabolic,
Cardiovascular, Renal
Type 2 diabetes, Heart failure,
Chronic kidney disease
EMPAGLIFLOZIN



Approved



Scotland
SMC2841

Genitourinary
Endometriosis
LINZAGOLIX



Approved



England
NICE TA937

Genitourinary
Nephropathy
BUDESONIDE

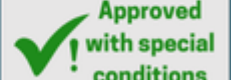


Approved
with special
conditions



England
NICE TA1074

Genitourinary
Nephropathy
SPARSENTAN



Approved
with special
conditions



England
NICE TA1100

Genitourinary
Neurogenic detrusor
overactivity
MIRABEGRON



Terminated

Pharmacological Technologies



Germany
IQWiG G25-23

Genitourinary
Phenylketonuria
SEPIAPTERIN



Ireland
HSE 21055

Genitourinary
Uterine fibroids
RELUGOLIX



Brazil
CONITEC

Genitourinary
Uterine fibroids
TRANEXAMIC ACID AND
LEVONORGESTREL



Germany
IQWiG A25-92

Infection
COVID-19
REMDESIVIR



Brazil
CONITEC

Infection
Hepatitis C
SOFOSBUVIR/
VELPATASVIR



Brazil
CONITEC

Infection
Human
immunodeficiency virus
BICTEGRAVIR/EMTRICITABINE
/TENOFVIR ALAFENAMIDE



Wales
AWTTC 3656

Infection
Human
immunodeficiency virus
CABOTEGRAVIR



Brazil
CONITEC

Infection
Tungiasis
DIMETHICONE



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Pharmacological Technologies



England
NICE TA1104

Musculoskeletal
Juvenile arthritis
SARILUMAB



Terminated



Wales
AWTTC 4522

Musculoskeletal
Juvenile arthritis
SARILUMAB



Excluded



Korea
HIRA 2025-169

Musculoskeletal,
Pregnancy, Skin
Multiple conditions - see
page for details
METHOTREXATE



Approved



Germany
IQWiG A25-86

Neurology
Friedreich's ataxia
OMAVELOXOLONE



Not
approved



France
HAS AP510

Neurology
Metachromatic
leukodystrophy
ATIDARSAGENE
AUTOTEMCEL



Approved



Scotland
SMC2805

Neurology
Spinal muscular
atrophy
NUSINERSEN



Approved
orphan drug
status



Brazil
CONITEC

Neurology, Endocrine
Parkinson's disease,
Hyperprolactinemia
BROMOCRIPTINE
MESYLATE



Not
approved



Brazil
CONITEC

Pregnancy
Postpartum
haemorrhage
CARBETOCIN



Not
approved

HTANGEL

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Pharmacological Technologies



England
NICE TA1102

Renal
Glomerulopathy
IPTACOPAN



Terminated



France
HAS AP501

Renal
Glomerulopathy
IPTACOPAN



Not
approved



Wales
AWTTC 5123

Renal
Glomerulopathy
IPTACOPAN



Excluded

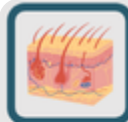


Korea
HIRA 2025-169

Respiratory,
Musculoskeletal
Interstitial pneumonitis,
Polymyositis,
Dermatomyositis
CYCLOSPORINE



Approved

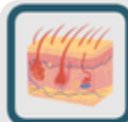


England
NICE TA1105

Skin
Acne vulgaris
CLASCOTERONE



Terminated

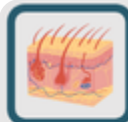


Wales
AWTTC 3853

Skin
Acne vulgaris
CLASCOTERONE



Excluded

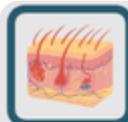


Wales
AWTTC 5110

Skin
Eczema
DELGOCITINIB



Excluded



France
HAS AP503

Skin
Epidermolysis bullosa
BEREMAGENE
GEPERPAVEC



Approved



Pharmacological Technologies



Ireland
HSE 25018

Skin
Hidradenitis
suppurativa
BIMEKIZUMAB

✓ **Approved**
with special
conditions



Korea
HIRA 2025-169

Skin, Renal,
Musculoskeletal, Blood,
Neurology
Multiple conditions - see
page for details
CYCLOSPORINE

✓ **Approved**



Korea
HIRA 2025-169

Skin, Surgery, Renal, Eye,
Neurology, Genetic &
Metabolic, Respiratory,
Musculoskeletal
Multiple conditions - see page
for details
MYCOPHENOLATE MOFETIL

✓ **Approved**



Korea
HIRA 2025-169

Surgery, Musculoskeletal,
Neurology, Renal
Stem cell transplant,
Rheumatoid arthritis,
Myasthenia gravis, Nephrotic
syndrome
TACROLIMUS

✓ **Approved**

Non-pharmacological Technologies



England
NICE IPG807

Cardiovascular
Heart failure

VENOARTERIAL
EXTRACORPOREAL
MEMBRANE OXYGENATION



England
NICE IPG808

Cardiovascular
Heart failure

VENOARTERIAL
EXTRACORPOREAL
MEMBRANE OXYGENATION



Diagnostic Testing



**Brazil
CONITEC**

**Genetic & Metabolic
ANCA-Associated
Vasculitis
ELISA TESTS**

**X Not
approved**



**England
NICE HTE34**

**Musculoskeletal
Fractures
AI TECHNOLOGIES**

**✓ Approved
with special
conditions**



**Brazil
CONITEC**

**Other
Transplant rejection
IMMUNOHISTOCHEMISTRY
AND ANTI-HLA ANTIBODIES
(DSA)**

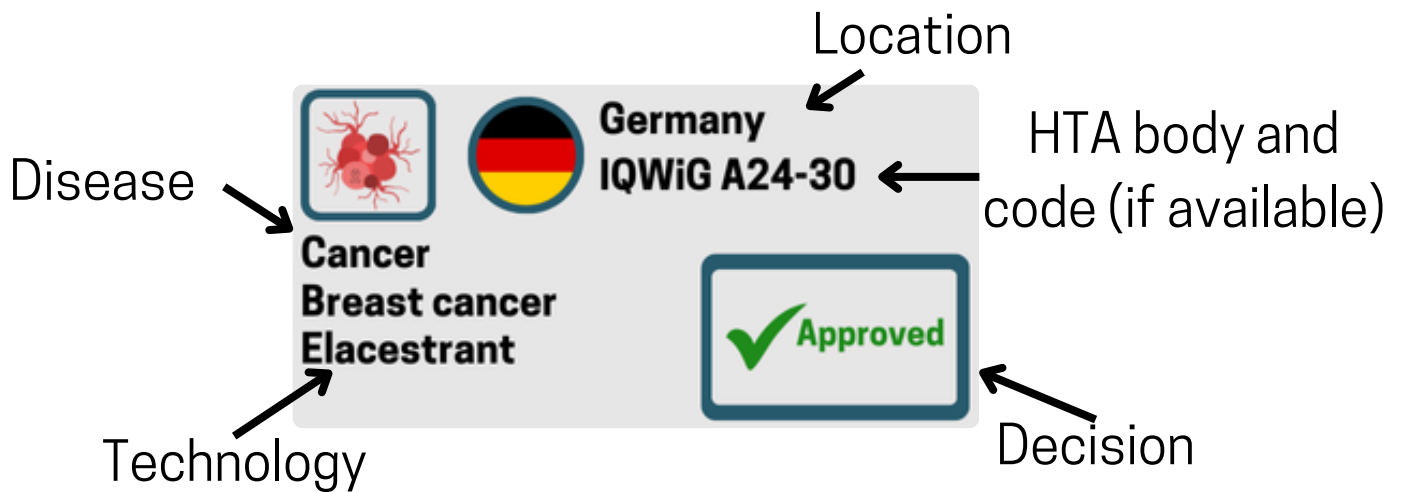
✓ Approved

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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