Crystallise Insights

HTANGEL

KEEPING YOU UP-TO-DATE ON INTERNATIONAL HTA DECISIONS

Issue 19: November 2024

Over half of cancer-related submissions were approved!

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

Good news for: **Durvalumab**, approved for small-cell lung cancer in France; **Teclistamab**, approved for multiple myeloma in France and England; and **Zanidatamab**, approved for biliary tract cancer in France.

Mixed news for: **Ixekizumab**, approved for active psoriatic arthritis but not approved for moderate-to-severe plaque psoriasis in Brazil; **Pembrolizumab**, approved for non-small-cell lung cancer in England but not in Scotland; and **Rituximab**, **dapsone** and **romiplostim**, approved for primary idiopathic thrombocytopenic purpura in Brazil in adults but not in children.

Bad news for: **Dupilumab**, not approved for COPD in France and Germany; **Nirsevimab**, not approved for RSV infection in Germany and Brazil; and **Vadadustat**, not approved for anaemia in Germany.

30 Approvals

14 with special arrangements
1 with orphan drug status

27 Not approved

3 Excluded submissions

4 Evidence reviews

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Pharmacological Technologies

England
NICE TA1019

Blood
Paroxysmal nocturnal haemoglobinuria
CROVALIMAB

Approved with special conditions

Brazil
CONITEC

Blood
Iron overload in sickle cell anemia
DEFERIPRONE

Not approved

England
NICE TA1018

Blood
Disease-related splenomegaly or symptoms in myelofibrosis
FEDRATINIB

Approved with special conditions

Brazil
CONITEC

Blood
Primary idiopathic thrombocytopenic purpura
RITUXIMAB, DAPSONE, ROMIPLOSTIM

Approved with special conditions

Brazil
CONITEC

Blood
Primary idiopathic thrombocytopenic purpura
RITUXIMAB, DAPSONE, ROMIPLOSTIM

Not approved

Germany
IQWiG A24-106

Blood
Symptomatic anemia
VADADUSTAT

Not approved

Germany
IQWiG A24-67

Blood
Anaemia
VADADUSTAT

Not approved

England
NICE TA1014

Cancer
ALK-positive non-small-cell lung cancer
ALECTINIB

Approved with special conditions

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Pharmacological Technologies

England
NICE TA1012

Cancer
Advanced systemic mastocytosis
AVAPRITINIB

Approved with special conditions

Scotland
SMC2695

Cancer
Diffuse large B-cell lymphoma
AXICABTAGENE CILOLEUCEL

Approved

France
HAS AP407

Cancer
Small cell lung cancer
DURVALUMAB

Approved

Wales
AWTTC 5302

Cancer
Resectable non-small-cell lung cancer
DURVALUMAB

Excluded

Germany
IQWiG A24-78

Cancer
Solid tumors
ENTRECTINIB

Not approved

Scotland
SMC2742

Cancer
Non-metastatic hormone-sensitive prostate cancer
ENZALUTAMIDE

Not approved

Germany
IQWiG A24-74

Cancer
Colorectal cancer
FRUQUINTINIB

Approved

Germany
IQWiG A24-66

Cancer
Cholangiocarcinoma
FUTIBATINIB

Not approved

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Pharmacological Technologies

Germany
IQWiG A24-77

Cancer
NSCLC
OSIMERTINIB

Not approved

France
HAS AP385

Cancer
Multiple myeloma
TECLISTAMAB

Approved

England
NICE TA1017

Cancer
Resectable non-small-cell lung cancer
PEMBROLIZUMAB

Approved with special conditions

England
NICE TA1015

Cancer
Relapsed/refractory multipe myeloma
TECLISTAMAB

Approved with special conditions

Scotland
SMC2688

Cancer
Resectable non-small-cell lung cancer
PEMBROLIZUMAB

Not approved

France
HAS AP404

Cancer
Biliary tract cancer
ZANIDATAMAB

Approved

Scotland
SMC2699

Cancer
Acute myeloid leukaemia
QUIZARTINIB

Approved

Argentina
IECS

Cardiovascular
Heart failure
SGLT-2I

Not approved

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Pharmacological Technologies

Scotland
SMC2697

Cardiovascular
Acute ischaemic stroke
TENECTEPLASE

✓ Approved

Scotland
SMC2701

Gastrointestinal
Eradication of Helicobacter pylori
BISMUTH SUBCITRATE POTASSIUM, METRONIDAZOLE, TETRACYCLINE HYDROCHLORIDE

✓! Approved with special conditions

England
NICE TA1016

Gastrointestinal
Primary biliary cholangitis
ELAFIBRANOR

✓! Approved with special conditions

Wales
AWTTC 3215

Gastrointestinal
Cholestatic pruritus
MARALIXIBAT

Excluded

Argentina
IECS

Genetic & Metabolic
Type 2 diabetes mellitus
CANAGLIFLOZIN, EMPAGLIFLOZIN, DAPAGLIFLOZIN

✓ Approved

Argentina
IECS

Genetic & Metabolic
Type 2 diabetes mellitus
CANAGLIFLOZIN, EMPAGLIFLOZIN, DAPAGLIFLOZIN

✗ Not approved

Argentina
IECS

Genetic & Metabolic
Type 2 diabetes mellitus
CANAGLIFLOZIN, EMPAGLIFLOZIN, DAPAGLIFLOZIN

✗ Not approved

England
NICE TA1020

Genetic & Metabolic
Hereditary transthyretin-related amyloidosis
EPLONTERSEN

✓! Approved with special conditions

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Pharmacological Technologies

Brazil
CONITEC

Genetic & Metabolic
Type 2 diabetes mellitus
FAST-ACTING INSULIN ANALOGUES

✓ Approved

Brazil
CONITEC

Genetic & Metabolic
Type 2 diabetes mellitus
LONG-ACTING INSULIN ANALOGUE

✓ Approved

Brazil
CONITEC

Genetic & Metabolic
Fabry disease
MIGALASTAT

✗ Not approved

Scotland
SMC2629

Genetic & Metabolic
Growth hormone deficiency
SOMAPACITAN

✓! Approved with special conditions

Scotland
SMC2631

Genitourinary
Uterine fibroids
LINZAGOLIX

✓! Approved with special conditions

Brazil
CONITEC

Infection
Cytomegalovirus
GANCICLOVIR, VALGANCICLOVIR

✓ Approved

Brazil
CONITEC

Infection
Refractory cytomegalovirus
MARIBAVIR

✓ Approved

Germany
IQWiG A24-82

Infection
RSV infections
NIRSEVIMAB

✗ Not approved

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Pharmacological Technologies

Brazil
CONITEC

Infection
RSV infections
NIRSEVIMAB

Not approved

Brazil
CONITEC

Infection
RSV infections
RESPIRATORY SYNCYTIAL VIRUS A AND B VACCINE (RECOMBINANT)

Not approved

Brazil
CONITEC

Musculoskeletal
Active psoriatic arthritis
IXEKIZUMAB

Approved

France
HAS AP395

Neurology
Metachromatic leukodystrophy
ATIDARSAGENE AUTOTEMCEL

Approved

Argentina
IECS

Neurology
Migraine prevention
FREMANEZUMAB

Not approved

Brazil
CONITEC

Neurology
Moderate and severe Alzheimer's disease
MEMANTINE HYDROCHLORIDE

Not approved

Wales
AWTTC 4273

Neurology
Relapsing multiple sclerosis
UBLITUXIMAB

Excluded

Germany
IQWiG G24-20

Renal
Primary immunoglobulin A nephropathy
SPARSENTAN

Approved orphan drug status

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Pharmacological Technologies

France
HAS AP393

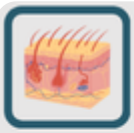
Respiratory
COPD
DUPILUMAB

Not approved

Germany
IQWiG A24-79

Respiratory
COPD
DUPILUMAB

Not approved



Germany
IQWiG A24-64

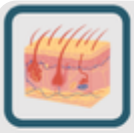
Skin
Hidradenitis suppurativa
BIMEKIZUMAB

Not approved

Brazil
CONITEC

Skin
Moderate to severe plaque psoriasis
IXEKIZUMAB

Not approved



Scotland
SMC2707

Skin
Moderate-to-severe atopic dermatitis
LEBRIKIZUMAB

Approved with special conditions

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Non-pharmacological Technologies

England
NICE IPG794

Cancer
Malignant biliary obstruction
ENDOSCOPIC BIPOLAR RADIOFREQUENCY ABLATION

Not approved

Korea
NECA HTA-2024-44

Musculoskeletal
Medial and lateral epicondylitis
AUTOLOGOUS WHOLE BLOOD APPLICATION

Not approved

Korea
NECA HTA-2024-47

Respiratory
Chronic rhinitis
CRYOABLATION USING SINUSOSCOPY

Approved

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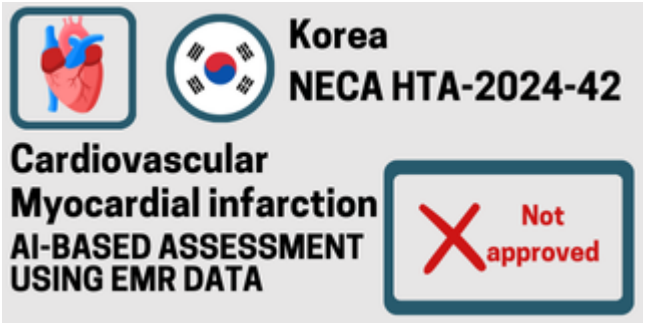
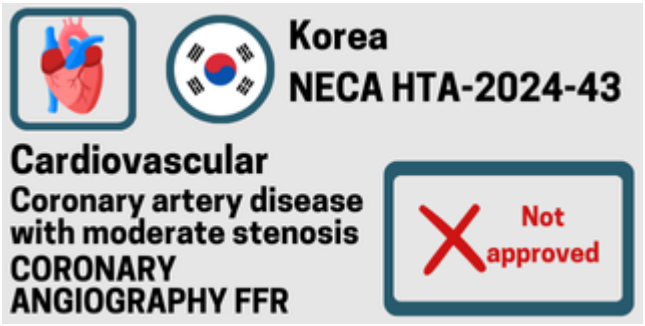
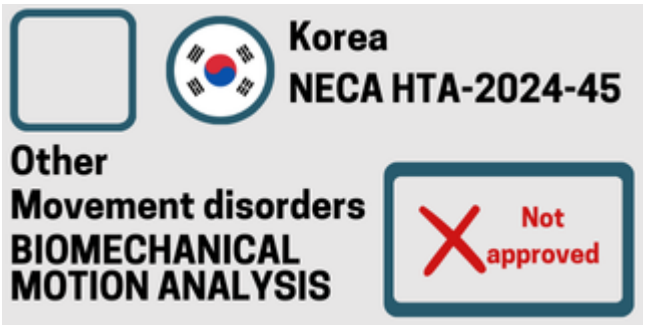
Diagnostic Testing







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Other Guidance

Canada
CDA HC0084

Cancer
NSCLC
IMMUNE CHECKPOINT INHIBITORS

Evidence review

Canada
CDA RE0050

Cancer
Advanced or metastatic NSCLC
IMMUNE CHECKPOINT INHIBITORS

Evidence review

Canada
CDA RC1554

Neurology
Seizures
MIDAZOLAM

Evidence review

USA
AHRQ

Other
Bone disease, kidney disease, sarcopenia
DIETARY PROTEIN INTAKE

Evidence review

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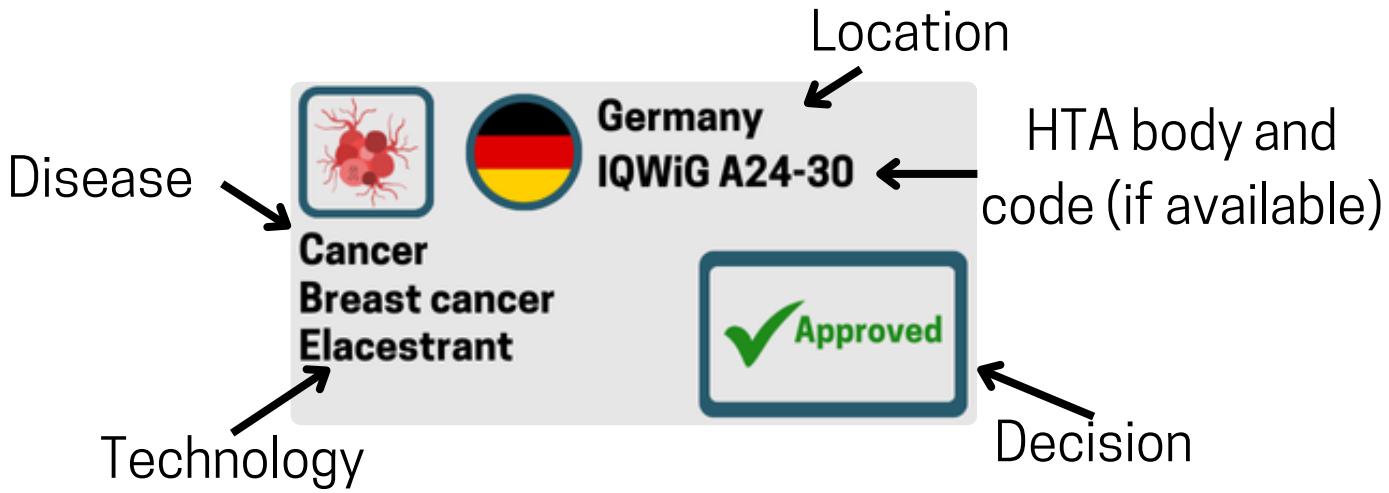
Further Information

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.



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For further information about HTAngel contact newsletter@crystallise.com

To speak to us about our services contact contact@crystallise.com

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