

HTANGEL

Keeping you up-to-date on
HTA decisions

Issue 41: September 2026

September brings major cancer approvals alongside sharp cross-market differences

This newsletter summarises final decisions from NICE, SMC, HAS & IQWiG from published reports in September 2026.

Good news

Atidarsagene autoemcel, approved for metachromatic leukodystrophy in Scotland; and patients with plexiform neurofibromas (PN) associated with neurofibromatosis type 1 (NF1), with **Mirdametinib** approved in England and **Selumetinib** approved in France.

Mixed news

Blinatumomab, approved for Philadelphia chromosome-negative (Ph-negative) CD19+ B-cell precursor acute lymphoblastic leukaemia in children but not adults in Germany; and **Sotatercept**, approved for pulmonary arterial hypertension in France but not in Scotland.

Bad news

Depemokimab, not approved for severe chronic rhinosinusitis with nasal polyps in Scotland; **Marstacimab**, not approved for the prevention of bleeding in haemophilia A or B in Germany; and **Selpercatinib**, not approved for advanced RET fusion-positive solid or thyroid cancers in Germany.

Approvals

20

Non-approvals

27

HTANGEL

Issue 41: September 2026

Pharmacological Technologies



Germany
IQWiG A26-56

Blood
Haemophilia B
MARSTACIMAB



Germany
IQWiG A26-59

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Germany
IQWiG A26-55

Blood
Haemophilia A
MARSTACIMAB



Germany
IQWiG A26-60

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Germany
IQWiG A26-53

Cancer
Chronic myeloid
leukaemia
ASCIMINIB



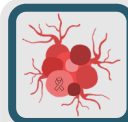
Germany
IQWiG A26-58

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Germany
IQWiG A26-57

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Germany
IQWiG A26-61

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



HTANGEL

Issue 41: September 2026

Pharmacological Technologies



Scotland
SMC2930

Cancer
Breast cancer
CAPIVASERTIB



Scotland
SMC2881

Cancer
Follicular lymphoma
EPCORITAMAB



England
NICE TA1195

Cancer
Multiple myeloma
DARATUMUMAB WITH
BORTEZOMIB, LENALIDOMIDE
AND DEXAMETHASONE



England
NICE TA1193

Cancer
Mantle cell
lymphoma
IBRUTINIB



England
NICE TA1190

Cancer
Endometrial cancer
DURVALUMAB WITH OR
WITHOUT OLAPARIB



Germany
IQWiG G26-13

Cancer
Acute lymphoblastic
leukaemia
INOTUZUMAB
OZOGAMICIN



Scotland
SMC2933

Cancer
Breast cancer
ELACESTRANT



England
NICE TA1194

Cancer
Multiple myeloma
ISATUXIMAB



HTANGEL

Issue 41: September 2026

Pharmacological Technologies



Scotland
SMC2972

Cancer
B-cell lymphoma,
Follicular lymphoma
LISOCABTAGENE
MARALEUCEL

Not
approved



Germany
IQWiG A26-98

Cancer
Prostate cancer
NIRAPARIB

Not
approved



Scotland
SMC2867

Cancer
Lung cancer
LORLATINIB

Approved



Germany
IQWiG A26-65

Cancer
Malignant melanoma
NIVOLUMAB/
RELATLIMAB

Approved
with special
conditions



France
HAS AP607

Cancer
Lung cancer
LURBINECTEDIN

Not
approved



Scotland
SMC2907

Cancer
Head and neck
cancer
PEMBROLIZUMAB

Approved



Germany
IQWiG A26-31

Cancer
Prostate cancer
NIRAPARIB

Not
approved



Germany
IQWiG A26-69

Cancer
Solid tumours
SELPERCATINIB

Not
approved

HTANGEL

Issue 41: September 2026

Pharmacological Technologies



Germany
IQWiG A26-70

Cancer
Thyroid cancer
SELPERCATINIB



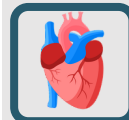
Scotland
SMC2973

Cardiovascular
Pulmonary arterial
hypertension
SOTATERCEPT



Germany
IQWiG A26-71

Cancer
Thyroid cancer
SELPERCATINIB



France
HAS AP603

Cardiovascular
Pulmonary arterial
hypertension
SOTATERCEPT



Scotland
SMC2974

Cancer
Oesophageal cancer
TORIPALIMAB



Scotland
SMC2971

Endocrine
Adrenal insufficiency
HYDROCORTISONE



Germany
IQWiG A26-64

Cardiovascular
Hypertrophic obstructive
cardiomyopathy
AFICAMTEN



Scotland
SMC2946

Gastrointestinal
Primary biliary
cholangitis
SELADELPAR



HTANGEL

Issue 41: September 2026

Pharmacological Technologies



Scotland
SMC2886

Genetic & Metabolic
Metachromatic leukodystrophy
ATIDARSAGENE
AUTOEMCEL



Germany
IQWiG A26-66

Musculoskeletal
Psoriatic arthritis
DEUCRAVACITINIB



Germany
IQWiG G26-16

Genetic & Metabolic
Duchenne muscular dystrophy
VAMOROLONE



England
NICE TA1192

Neurology
Neurofibromatosis
MIRDAMETINIB



Germany
IQWiG A26-67

Infection
Respiratory syncytial virus
CLESROVIMAB



Scotland
SMC2877

Neurology
Spinal muscular atrophy
NUSINERSEN



Germany
IQWiG G26-12

Infection
Tuberculosis
PRETOMANID



France
HAS AP602

Neurology
Neurofibromatosis
SELUMETINIB



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Issue 41: September 2026

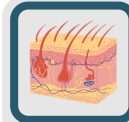
Pharmacological Technologies



Germany
IQWiG A26-26

Other
Immunoglobulin G4-
related disease
INEBILIZUMAB

Not
approved



England
NICE TA1191

Skin
Prurigo nodularis
NEMOLIZUMAB

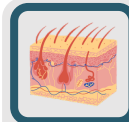
Not
approved



Germany
IQWiG A26-97

Other
Immunoglobulin G4-
related disease
INEBILIZUMAB

Not
approved



Germany
IQWiG A26-62

Skin
Urticaria
REMIBRUTINIB

Not
approved



Scotland
SMC2970

Respiratory
Rhinosinusitis, Nasal
polyps
DEPEMOKIMAB

Not
approved



Germany
IQWiG A26-63

Skin
Acne vulgaris
CLASCOTERONE

Not
approved

HTANGEL

Issue 41: September 2026

Diagnostic Testing



England
NICE HTG781

Eye

Age-related macular
degeneration

DIGITAL TECHNOLOGIES TO
SUPPORT HOME MONITORING
OF VISION CHANGES

 **Not
approved**



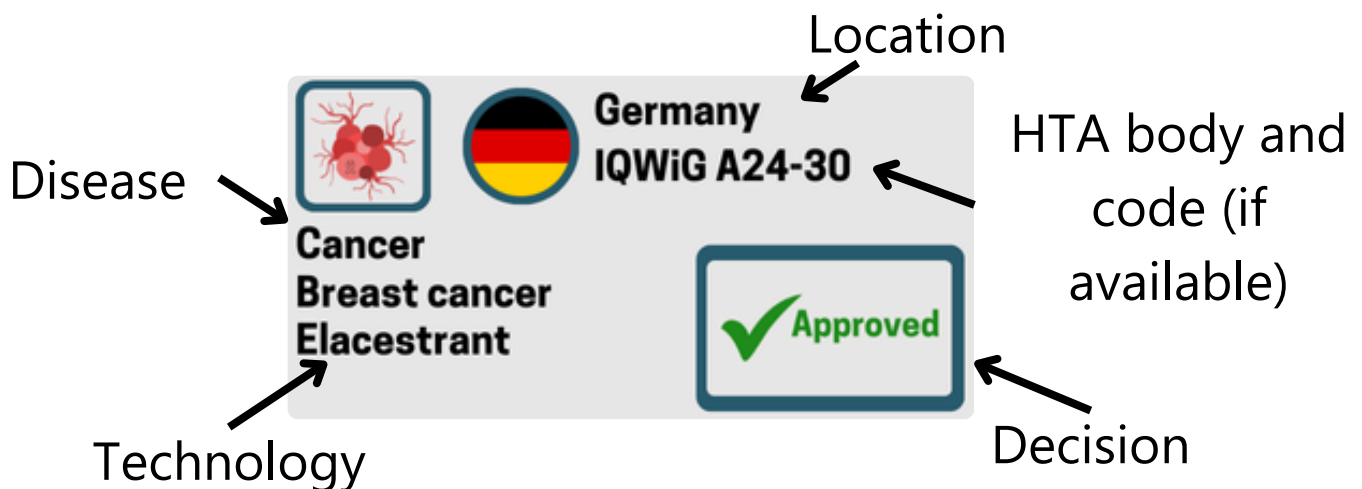
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Issue 41: September 2026

Further Information

HTAngel is designed to help keep you up to date with the latest HTA decisions from NICE, SMC, HAS & IQWiG.

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.

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