Aucatzyl

United Kingdom · access guide

Aucatzyl access in the United Kingdom: the Specials Licence pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Aucatzyl (obecabtagene autoleucel) is a CD19-directed autologous CAR-T cell therapy from Autolus Therapeutics, a UK-headquartered (London Stevenage) biotech company. The US FDA granted approval in November 2024 for adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (B-ALL). The MHRA granted UK marketing authorisation, and NICE has progressed Aucatzyl through technology appraisal with NHS England Specialised Commissioning preparing the implementation arrangements. Aucatzyl is among the first UK-discovered CAR-T cell therapies to receive UK regulatory approval and is delivered at the JACIE-accredited UK cell therapy centres.

The medicine has a distinctive lower-affinity CD19 binding profile designed to reduce the severity of cytokine release syndrome (CRS) and ICANS compared with earlier-generation CD19-directed CAR-T cell therapies. The clinical data from the FELIX trial demonstrated complete remission rates in the 70 to 80% range in heavily pre-treated adult B-ALL with a manageable safety profile.

Why UK adult B-ALL patients pursue Aucatzyl

Adult B-ALL is a rare and aggressive haematological malignancy with a less favourable prognosis than paediatric B-ALL. Patients with relapsed or refractory disease after first-line induction and consolidation have limited treatment options. The CD19-directed CAR-T cell therapies (tisagenlecleucel, brexucabtagene autoleucel, and now obecabtagene autoleucel) have transformed the relapsed/refractory adult B-ALL landscape. Aucatzyl's distinctive lower-affinity binding profile aims to deliver the efficacy of CAR-T cell therapy with a reduced CRS and ICANS burden, potentially expanding the eligible population to patients with comorbidities or high disease burden who might be at higher risk on the older-generation CAR-T products.

UK access friction includes the centre slot capacity, the NICE-recommended eligibility threshold, and the operational coordination across leukapheresis, manufacture, conditioning, and infusion. Private supply through the Specials route handles cases sitting outside the NHS eligibility threshold.

The Specials Licence pathway for Aucatzyl in the UK

Aucatzyl holds UK marketing authorisation and is supplied through Autolus's UK specialty distribution chain to JACIE-accredited UK cell therapy centres. The standard NHS route is via NICE technology appraisal and NHS England commissioning once the implementation arrangements are in place. The Specials Licence framework is relevant for patients outside the NICE criteria but clinically appropriate per their haematologist's judgment.

The clinical infrastructure required is the same as other CD19-directed CAR-T therapies: autologous leukapheresis at the treating centre, transfer to the Autolus manufacturing facility for CAR-T manufacture, cryopreserved return, conditioning chemotherapy (typically fludarabine plus cyclophosphamide), infusion, and intensive monitoring for CRS and ICANS. The lower CRS and ICANS profile compared with older-generation CAR-T may shift some patients to outpatient or step-down monitoring after initial inpatient observation, depending on the centre's protocol.

Where Aucatzyl is delivered in the UK

Aucatzyl delivery requires a JACIE-accredited adult cell therapy centre with B-ALL and CD19-directed CAR-T experience. The principal UK adult B-ALL CAR-T centres include University College London Hospitals (UCLH, a flagship UK B-ALL and CAR-T centre), King's College Hospital London, The Royal Marsden NHS Foundation Trust, the Christie and Manchester Royal Infirmary, Newcastle upon Tyne Hospitals, the Queen Elizabeth Hospital Birmingham, Beatson West of Scotland Cancer Centre Glasgow, and Belfast City Hospital. UCLH has particularly strong adult B-ALL CAR-T experience and was a major participant in the FELIX registration trial.

The dispensing pharmacy at the treating centre holds Aucatzyl, tocilizumab and anti-IL-6 backup, corticosteroid supply for ICANS management, and the inpatient antibiotic and inotrope stock required for CRS management.

Real cost picture for Aucatzyl in the UK

Aucatzyl's US list price is approximately USD 525,000 for the one-time infusion, similar to other CAR-T cell therapies. At 0.79 GBP to 1 USD the product converts to roughly GBP 415,000. NHS contracted pricing under any eventual NICE-recommended commissioning agreement would reflect a confidential commercial discount.

The full UK cost stack for a private Aucatzyl case extends to the leukapheresis procedure, the conditioning chemotherapy, the infusion admission, the inpatient monitoring stay (with potentially lower acuity given the lower CRS and ICANS profile), tocilizumab and corticosteroid medication, and follow-up bone marrow and minimal residual disease assessment. For a private UK Aucatzyl case the all-in cost typically lands in the GBP 470,000 to GBP 560,000 range. UK private medical insurance does not typically fund CAR-T cell therapies on standard policies.

Typical timeline for Aucatzyl in the UK

Aucatzyl's timeline mirrors other autologous CAR-T cell therapies. The realistic timeline runs as follows: Week 0 to 2 is the clinical assessment, eligibility confirmation, and centre slot booking. Week 2 to 3 is leukapheresis. Week 3 to 7 is the autologous CAR-T manufacture and quality release (typical Aucatzyl manufacture window is approximately 4 weeks). Week 7 is the conditioning chemotherapy and CAR-T infusion. Week 7 to 11 is the inpatient monitoring and early follow-up.

What your UK haematology consultant needs to provide

The treating UK consultant haematologist with adult B-ALL subspecialty expertise is the prescribing physician of record. The clinical packet typically includes the adult B-ALL diagnosis with cytogenetics, the documented relapsed or refractory status (prior induction and consolidation regimen, response, CD19 expression confirmation, minimal residual disease status), current performance status, organ function panel, CNS disease assessment (CSF cytology, MRI if CNS involvement is suspected), and the centre's CRS and ICANS management protocol.

Common questions about Aucatzyl in the UK

Will the NHS fund Aucatzyl? NICE technology appraisal is in progress and NHS England Specialised Commissioning is preparing the implementation arrangements. The clinical community expectation is for a positive recommendation given the unmet need in relapsed/refractory adult B-ALL.

How does Aucatzyl compare to other CD19 CAR-T cell therapies? Aucatzyl is a fast-off lower-affinity CD19 binder designed to reduce CRS and ICANS while preserving efficacy. Brexucabtagene autoleucel (Tecartus) is the older-generation CD19-directed CAR-T for adult B-ALL. Tisagenlecleucel (Kymriah) is licensed primarily for paediatric and young adult B-ALL. The choice depends on patient profile, centre experience, and the specific FELIX trial inclusion criteria comparison.

Why is the lower CRS and ICANS profile important? CRS and ICANS are the principal acute toxicities of CD19-directed CAR-T cell therapy. Severe CRS requires intensive care, vasopressor support, and tocilizumab; severe ICANS can cause seizures, cerebral oedema, and significant long-term neurological consequences. A CAR-T product with a meaningfully lower severe CRS and ICANS incidence broadens the eligible patient population to those with comorbidities, high disease burden, or other risk factors for CAR-T toxicity.

Is Aucatzyl available for paediatric patients? The UK marketing authorisation covers adult patients. Paediatric B-ALL CAR-T is typically delivered through the tisagenlecleucel (Kymriah) pathway for paediatric and young adult B-ALL.

What is Autolus's UK manufacturing footprint? Autolus operates a UK manufacturing facility at the Stevenage Bioscience Catalyst that supports its CAR-T cell therapy programme. This UK manufacturing presence is a distinctive feature of Aucatzyl among CAR-T products commercially available in the UK.

Where Reserve Meds fits in Aucatzyl cases

Reserve Meds is a US-based concierge coordinator. For Aucatzyl our role is most relevant for UK patients pursuing parallel routes outside NHS commissioning, for documentation support across the multi-week manufacture and infusion cycle, and for cross-market continuity of care. We do not replace your UK haematology consultant or the JACIE-accredited cell therapy centre. Aucatzyl's UK manufacturing presence simplifies some of the cross-border logistics typically involved in CAR-T cell therapy access.

The Yellow Card pharmacovigilance pathway for Aucatzyl

The MHRA Yellow Card scheme is the UK's national pharmacovigilance reporting system. Healthcare professionals, patients, and carers can report suspected adverse drug reactions, medical device incidents, defective medicines, and counterfeit medicines through the scheme. For specialty medicines accessed through the Specials Licence pathway, Yellow Card reporting is the operational mechanism that connects the UK clinical experience back to the global pharmacovigilance dataset that the MHRA, FDA, EMA, and other regulators rely on.

For Aucatzyl specifically, Reserve Meds coordinates the pharmacovigilance reporting chain in three ways. First, the prescribing UK consultant or the dispensing pharmacy submits any suspected adverse reactions through the Yellow Card scheme as standard practice. Second, the manufacturer's UK pharmacovigilance contact receives the case report through the standard regulatory channel and connects the case to the global safety database. Third, where the patient's clinical follow-up continues across markets, Reserve Meds provides the documentation continuity that lets the patient's consultants and the manufacturer's safety team coordinate across borders.

The MHRA also operates the Black Triangle (inverted black triangle) safety monitoring scheme for medicines that are under additional monitoring (typically newer medicines or medicines for which additional safety data are being collected). The Yellow Card scheme works the same way for Black Triangle medicines but with heightened attention to reporting.

UK consumer protection and patient rights for Aucatzyl

UK patients accessing specialty medicines through private pharmacy supply have the same consumer protections that apply to any UK regulated medicine purchase. The Care Quality Commission regulates private healthcare providers in England; Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Regulation and Quality Improvement Authority in Northern Ireland are the parallel regulators in the devolved nations. The General Pharmaceutical Council regulates pharmacy professionals and registered pharmacy premises. The General Medical Council regulates doctors. The Nursing and Midwifery Council regulates nurses, including specialist nurses involved in cell therapy and homecare administration.

For UK patients accessing Aucatzyl, the relevant protections include the prescribing consultant's professional duty under GMC Good Medical Practice, the dispensing pharmacist's professional standards under General Pharmaceutical Council standards, the homecare provider's regulatory framework (where applicable), and the manufacturer's UK pharmacovigilance obligations. Reserve Meds operates as a US-based coordinator and is subject to US regulatory frameworks for our US-side operations; we do not replace or substitute for UK consumer protections, which the UK clinical and pharmacy chain provides directly.

Special considerations for international UK residents and dual-citizen families

The UK is home to a substantial population of international residents, dual-citizen families, and patients who spend significant time across multiple markets. For Aucatzyl cross-border continuity of care across the UK, the United States, the Gulf, India, and other markets is a recurring operational pattern. Reserve Meds is structured to support this cross-market reality with a single coordinator who understands the regulatory frameworks across the relevant jurisdictions, the documentation portability across markets, and the operational connection back to the UK clinical team during periods of UK residence.

UK patients who spend time in the United States may also pursue treatment at a US authorised treatment centre when this is clinically or operationally preferable. Reserve Meds provides the US-side liaison, the documentation packet for the US treatment centre, and the operational support across the UK-US clinical handover both at the start and on return to the UK for long-term follow-up.

Where to read more about Aucatzyl and the UK Specials pathway

Reserve Meds publishes detailed reference material across the regulatory pathways, country specifics, and condition-specific access guides. For the regulatory framework underlying the UK route to Aucatzyl, the named-patient pathway overview covers the international framework and the United Kingdom country deep-dive covers the MHRA Specials Licence, NICE technology appraisal, NHS England Specialised Commissioning, and the dispensing infrastructure in detail. The MHRA's own guidance on the supply of unlicensed medicinal products (often called the MHRA Guidance Note 14) provides the formal regulatory framing for prescribers and pharmacists. The General Pharmaceutical Council's standards on the dispensing of unlicensed medicines provide the pharmacy practice framework.

For UK patient information on the NHS-funded pathway, the National Institute for Health and Care Excellence (NICE) publishes the relevant technology appraisal guidance, and NHS England Specialised Commissioning publishes the corresponding clinical commissioning policy. Patients can search the NICE website for the specific technology appraisal that applies to their medicine and indication.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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