Breyanzi

United Kingdom · access guide

Breyanzi access in the United Kingdom: the Specials Licence pathway

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

Quick orientation

Breyanzi (lisocabtagene maraleucel, liso-cel) is Bristol Myers Squibb and Juno Therapeutics' CD19-directed autologous CAR-T cell therapy. The US FDA initially granted approval in February 2021 for adults with relapsed or refractory large B-cell lymphoma and has progressively expanded the indication to include relapsed/refractory chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma, follicular lymphoma, mantle cell lymphoma, and marginal zone lymphoma. The MHRA granted UK marketing authorisation, and NICE has issued positive technology appraisal recommendations across selected indications. Breyanzi is delivered at the JACIE-accredited UK cell therapy centres alongside Yescarta (axicabtagene ciloleucel) and Kymriah (tisagenlecleucel), the other licensed CD19-directed CAR-T options for B-cell lymphoma.

Breyanzi's distinctive feature is the defined 1:1 CD4:CD8 T-cell composition of the manufactured product and the favourable CRS and ICANS profile in pivotal trials, which has positioned the medicine as a CAR-T option suitable for patients with comorbidities or other risk factors that might preclude the older-generation CAR-T products.

Why UK lymphoma patients pursue Breyanzi

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) is the principal indication for CD19-directed CAR-T cell therapy. The TRANSCEND-NHL-001 (Breyanzi), ZUMA-1 (Yescarta), and JULIET (Kymriah) registration trials transformed the outcome landscape for relapsed/refractory DLBCL. The choice between the three CAR-T options is a haematologist's clinical decision based on the patient's specific profile, the centre's experience, and the operational considerations.

UK access friction includes the centre slot capacity at JACIE-accredited UK CAR-T centres, the NICE-recommended eligibility criteria, and the operational coordination across leukapheresis, manufacture, conditioning, and infusion. Private supply through the Specials route handles cases sitting outside the NHS eligibility threshold or pursuing parallel routes.

The Specials Licence pathway for Breyanzi in the UK

Breyanzi holds UK marketing authorisation and is supplied through Bristol Myers Squibb's UK specialty distribution chain to JACIE-accredited UK CAR-T centres. The standard NHS route is via NICE technology appraisal and NHS England Specialised Commissioning. The Specials Licence framework supports private patients pursuing parallel routes and cases outside the NICE-recommended eligibility threshold.

The clinical infrastructure required is the same as other CD19-directed CAR-T cell therapies: autologous leukapheresis, manufacture, cryopreserved return, fludarabine plus cyclophosphamide conditioning, infusion, and intensive monitoring for CRS and ICANS for at least 28 days post-infusion. Breyanzi's favourable safety profile in TRANSCEND-NHL-001 may permit outpatient or hybrid step-down monitoring at experienced centres.

Where Breyanzi is delivered in the UK

Breyanzi delivery requires a JACIE-accredited adult cell therapy centre with CD19-directed CAR-T experience. The UK centres delivering CD19 CAR-T cell therapy for large B-cell lymphoma include King's College Hospital London, University College London Hospitals (UCLH), 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. For private patients HCA Healthcare UK at University College Hospital and The Royal Marsden Private Care are the established private CAR-T routes.

The post-infusion monitoring requirement of 28 days proximate to the treating centre is mandatory; patients live within a defined radius of the centre during this period and have caregivers available for symptom recognition.

Real cost picture for Breyanzi in the UK

Breyanzi's US list price is approximately USD 487,200 for the one-time infusion. At 0.79 GBP to 1 USD the product converts to roughly GBP 385,000. NHS contracted pricing under the NICE-recommended commissioning agreement reflects a confidential commercial discount.

The full UK cost stack for a private Breyanzi case extends to the leukapheresis procedure, the bridging therapy during the manufacture window, the conditioning chemotherapy, the infusion admission, the inpatient monitoring stay, tocilizumab and corticosteroid medication, and follow-up imaging and bone marrow assessment. For a private UK Breyanzi case the all-in cost typically lands in the GBP 440,000 to GBP 520,000 range. UK private medical insurance does not typically fund CAR-T cell therapies on standard policies.

Typical timeline for Breyanzi in the UK

Breyanzi'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 (Breyanzi manufacture window is approximately 4 weeks). Week 7 is the bridging therapy if needed, 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 B-cell lymphoma subspecialty expertise is the prescribing physician of record. The clinical packet typically includes the lymphoma diagnosis with histology (DLBCL, transformed indolent lymphoma, primary mediastinal large B-cell lymphoma, follicular lymphoma grade 3B, mantle cell lymphoma, CLL, marginal zone lymphoma, depending on indication), the prior therapy log, the CD19 expression confirmation, current PET-CT staging, organ function panel, CNS disease assessment, and the centre's CRS and ICANS management protocol.

Common questions about Breyanzi in the UK

Will the NHS fund Breyanzi? NICE has issued positive technology appraisal recommendations across selected B-cell lymphoma indications. NHS England Specialised Commissioning funds Breyanzi within these recommendations.

How does Breyanzi compare to Yescarta and Kymriah? All three are CD19-directed autologous CAR-T cell therapies for B-cell lymphoma. Breyanzi has a defined 1:1 CD4:CD8 T-cell product composition and a favourable CRS and ICANS profile in TRANSCEND-NHL-001. Yescarta has the longest CAR-T experience in large B-cell lymphoma. Kymriah has the broadest age range across paediatric and adult indications. Head-to-head trials are limited; the choice is a haematologist's clinical decision.

What is the manufacture turnaround? The Breyanzi autologous manufacture turnaround is typically approximately 4 weeks from apheresis to infusion-ready product.

Can Breyanzi be delivered in an outpatient setting? Breyanzi's favourable CRS and ICANS profile in pivotal trials has supported outpatient infusion at selected experienced centres. The post-infusion monitoring requirement of 28 days proximate to the treating centre still applies.

What about second-line use in DLBCL? The TRANSFORM trial supported Breyanzi's earlier use in second-line transplant-eligible patients with relapsed/refractory DLBCL. NICE and NHS England commissioning may evolve in this earlier-line setting.

Will my UK private medical insurance cover Breyanzi? UK private medical insurance does not typically fund CAR-T cell therapies on standard policies. Self-funding is the operative reality for private UK Breyanzi cases.

Where Reserve Meds fits in Breyanzi cases

Reserve Meds is a US-based concierge coordinator. For Breyanzi our role spans UK patients pursuing parallel routes outside NHS commissioning, documentation support across the multi-week manufacture and infusion cycle, and cross-market continuity of care for international patients. We do not replace your UK haematology consultant or the JACIE-accredited cell therapy centre.

The Yellow Card pharmacovigilance pathway for Breyanzi

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 Breyanzi 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 Breyanzi

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 Breyanzi, 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 Breyanzi 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 Breyanzi 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 Breyanzi, 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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