Trikafta

United Kingdom · access guide

Trikafta (Kaftrio) access in the United Kingdom: the Specials Licence pathway

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

Quick orientation

Trikafta is the US brand name for Vertex Pharmaceuticals' triple-combination CFTR modulator elexacaftor/tezacaftor/ivacaftor; the medicine is marketed in the United Kingdom and the European Union under the brand name Kaftrio. The MHRA granted UK marketing authorisation, and NICE issued TA715 in 2022 recommending Kaftrio for cystic fibrosis patients aged 6 years and older with at least one F508del mutation, within an NHS England commissioning arrangement. The indication has expanded over subsequent label updates to younger paediatric age bands (2 to 5 years, with further work on under-2 paediatric indications), and to a wider range of CFTR mutations responsive to the triple combination.

The UK access situation for Kaftrio is strong: NHS England commissions across the NICE-recommended population, the specialist CF centre network is well-established, and the medicine is among the most-used CFTR modulators globally. The Specials Licence pathway is relevant for paediatric patients sitting just outside the licensed age band, for specific CFTR mutation cases not yet on the label, and for the US-branded Trikafta presentation where the UK Kaftrio supply has a specific pack format gap.

Why UK CF patients pursue Trikafta via cross-border supply

The principal UK CF supply route is Kaftrio through NHS commissioning via specialist CF centres. UK families pursue cross-border Trikafta supply in three scenarios. First, paediatric patients sitting just below the current licensed age band whose paediatric CF consultant judges the medicine appropriate. The MHRA and EMA labels have expanded progressively (from 12 years to 6 years to 2 to 5 years), but the under-2 age band requires the Specials route until further label expansion. Second, specific CFTR mutation patients where the patient's genotype is not yet listed in the EU/UK SmPC but the equivalent FDA label or the manufacturer's in vitro responsiveness data support use. Third, very rarely, supply chain pack format issues where the UK Kaftrio supply chain temporarily lacks a specific pack and the US Trikafta presentation is required.

The CF clinical community in the UK has very high familiarity with CFTR modulators; the operational and clinical decision-making is well-established.

The Specials Licence pathway for Trikafta in the UK

For the standard NHS route, Kaftrio is the UK-licensed product and is supplied through Vertex's UK specialty distribution to NHS CF centres. For the Specials route under regulations 167 and 168 of the Human Medicines Regulations 2012, a UK consultant CF physician's prescription supports import of either the US Trikafta presentation or the UK Kaftrio presentation through a UK Specials Licence holder, for cases where the local Kaftrio supply does not match the clinical need.

The clinical infrastructure for CFTR modulator therapy is well-established at UK specialist CF centres. The eligibility workup includes CFTR genotype confirmation, baseline lung function (FEV1, FVC), sweat chloride, BMI, liver function panel, and ophthalmological assessment (cataract screening recommended at baseline and annually given the small association with cataracts in paediatric patients). The dosing is age-banded and includes a morning dose of elexacaftor/tezacaftor/ivacaftor and an evening dose of ivacaftor, taken with fat-containing food.

Where Trikafta (Kaftrio) is dispensed in the UK

The UK specialist CF centre network is among the most developed in the world. The principal adult CF centres include the Royal Brompton Hospital and Harefield London, Papworth Hospital Cambridge, Frimley Park Hospital, Manchester Adult CF Centre at Wythenshawe, Birmingham Adult CF Centre at Heartlands, Leeds Adult CF Centre at St James's, Newcastle upon Tyne Hospitals, the Western General Edinburgh, and the Cardiff Adult CF Centre at Llandough. Paediatric CF centres include Great Ormond Street, the Royal Brompton paediatric service, Manchester Children's Hospital, Birmingham Children's Hospital, Sheffield Children's, the Royal Hospital for Children Glasgow, and Bristol Royal Hospital for Children.

Kaftrio is dispensed through the specialist CF centre's pharmacy or through homecare providers contracted with the local CF service. The standard dispensing pattern is monthly supply with regular CF clinic follow-up.

Real cost picture for Trikafta (Kaftrio) in the UK

Trikafta's US WAC is approximately USD 327,000 per year at the standard adult dose. At 0.79 GBP to 1 USD the US WAC equivalent converts to approximately GBP 258,000 per year. NHS contracted pricing for Kaftrio under the NHS England commissioning agreement reflects a confidential commercial discount; published research on CFTR modulator pricing suggests the agreed UK net price is materially below US list, although the exact figure is commercially confidential.

For private UK supply through a UK-licensed specialty pharmacy the price typically lands below US WAC equivalent depending on supplier and quantity. UK private medical insurance generally does not fund CFTR modulators on standard policies; the principal funder is NHS commissioning. Self-funding for Trikafta or Kaftrio in advance of NHS commissioning is rare given the NHS access is in place across the NICE-recommended population.

Typical timeline for Trikafta (Kaftrio) in the UK

For an NHS-routed case the timeline from CF clinic assessment to first prescription is typically 1 to 8 weeks depending on the centre's queue and the baseline workup. The medicine is a continuous oral therapy. For a Reserve Meds cross-border Specials case (typically for paediatric off-label or specific mutation cases) the documentation and US-side sourcing completes within 2 to 3 weeks; the UK CF centre's clinical follow-up and monitoring schedule continues as standard.

What your UK CF consultant needs to provide

The treating UK consultant CF physician (adult CF specialist or paediatric CF specialist) is the prescribing physician of record. The clinical packet typically includes the CF diagnosis with sweat chloride, the CFTR genotype confirmation (both alleles), baseline lung function (FEV1 percent predicted, FVC), nutritional status and BMI, liver function panel, ophthalmological baseline (cataract screening), pancreatic status, and the dosing band by age and weight.

The MHRA Yellow Card scheme is the active pharmacovigilance route for any suspected adverse drug reaction including liver function abnormalities, cataract development in paediatric patients, mental health changes (mood, anxiety, depression have been reported), and rash.

Common questions about Trikafta (Kaftrio) in the UK

Is Kaftrio the same as Trikafta? Yes. Trikafta is the US brand name and Kaftrio is the UK and EU brand name for the same medicine, elexacaftor/tezacaftor/ivacaftor.

Will the NHS pay for Kaftrio? Yes. NICE TA715 recommends Kaftrio for CF patients aged 6 years and older with at least one F508del mutation, within an NHS England commissioning arrangement. The indication and age band have expanded over subsequent label updates. NHS Scotland, Wales, and Northern Ireland follow equivalent commissioning routes.

What about younger paediatric patients? The MHRA label has expanded progressively. As of mid-2026 the licensed age band reaches down to 2 years for selected paediatric indications, with the under-2 segment depending on further label updates. Specials route access is the route for under-licensed patients where the paediatric CF consultant judges appropriate.

What CFTR mutations are covered? The MHRA Kaftrio label covers patients with at least one F508del mutation. The label has been progressively expanded to include additional minimal-function and gating mutations responsive to the triple combination. Cases with mutations on the FDA Trikafta label but not yet on the UK Kaftrio label may be routed through the Specials framework.

What about cataract screening for paediatric patients? Cataract development has been reported in paediatric patients on ivacaftor-containing regimens. The recommendation is for baseline ophthalmological examination before initiation and annually during therapy in paediatric patients.

What about mental health monitoring? Mood, anxiety, and depression changes have been reported in some patients on Kaftrio. Patients and families should be counselled to report any psychiatric symptom changes. The CF clinical team incorporates mental health screening into the routine follow-up schedule.

Where Reserve Meds fits in Trikafta (Kaftrio) cases

Reserve Meds is a US-based concierge coordinator. For Trikafta or Kaftrio our role is limited to specific Specials route scenarios: paediatric patients sitting outside the current UK label, specific CFTR mutation cases not yet on the UK label, and supply chain gap cases. The standard UK NHS route through specialist CF centres and the NHS England commissioning agreement is the principal access pathway and is well-established. We do not replace your UK consultant CF physician or the specialist CF centre.

The Yellow Card pharmacovigilance pathway for Trikafta

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 Trikafta 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 Trikafta

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 Trikafta, 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 Trikafta 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 Trikafta 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 Trikafta, 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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