

**Head of Contracting and
Head of Information Governance**
East of England Acute Providers

Rare Disease Registration Service
National Disease Registration Service
Public Health England

www.gov.uk/phe

Via email only

phe.ncardrsd@nhs.net

1st October 2021

Dear Provider

Re: High Cost Drug Patient Data to support the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

We are writing to you as a healthcare provider commissioned to provide high-cost drugs funded by NHS England Specialised Commissioning for patients with rare diseases, either via the NHS England Provider Eligibility List (PEL) or because you manage these patients in collaboration with a centre commissioned to provide specialised services.

This letter explains how patient information submitted to NHS England and NHS Improvement (NHS E & I) on the prior approval system (currently Blueteq) will be shared with the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) and the legal basis for doing so. NCARDRS is part of the National Disease Registration Service (NDRS), which is part of Public Health England (PHE) and records people with congenital abnormalities and rare diseases across the whole of England. The registration service provides a resource for clinicians to support high quality clinical practice, including epidemiology and monitoring of the frequency, nature, cause and outcomes of these disorders.

To identify those patients who have received specific high-cost drugs for the treatment of a rare disease, NHS E and I are working with NCARDRS and will instruct Blueteq to provide the required data to NCARDRS (including NHS number and date of birth). Blueteq data is already shared with NDRS for cancer indications to support the national cancer registration and analysis service (NCRAS) and has proved to be exceptionally efficient and valuable. Data supplied for rare disease patients will support future NHS E and I commissioning decisions for these and future drugs as well as current work being undertaken to understand the impact of COVID-19 on rare disease patients.

NHS E and I do not have an exemption to the Common Law Duty of Confidentiality and therefore cannot access the identifiable patient data directly. NCARDRS has permission to process confidential patient information (without prior patient consent) afforded through Regulation 5 of The Health Service (Control of Patient Information)

Regulations 2002. Specific permission has been granted to PHE through the HRA CAG process for Regulation 5 (Ref: CAG10-02(d)/2015) access to confidential patient information without consent through Section 60 of the Health and Social Care Act 2001 as re-enacted by Section 251 of the NHS Act 2006.

This specific exemption allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes relating to the Public Health England National Congenital Anomaly and Rare Disease Registration Service. From 1st October 2021, the National Disease Registration Service will move to NHS Digital and permission to process confidential patient information and will be directed by the Secretary of State through Section 254 of the Health and Social Care Act. More information about this can be found at NHS Digital's website, or by contacting phe.ncardrsrd@nhs.net. PHE will process the identifiable trust data held in Blueteq already collected from all acute trusts in England and incorporate this data into the NCARDRS registration process.

National data opt outs do not apply to the national disease registration, and NCARDRS has implemented a policy of supporting opt out requests from patients. This is publicised through the NCARDRS website and patient information leaflet, as well as through NDRS' engagement work with rare diseases patient groups and representatives. If you would like to request copies of the leaflet, please email NDRSengagement@nhs.net or you can find more information, and access the leaflet, from the National Disease Registration Service webpage <https://www.ndrs.nhs.uk/>.

You are advised that it may be appropriate to update your organisation's privacy notice to ensure that patients are made aware that their data is being shared with NDRS for the purposes described above.

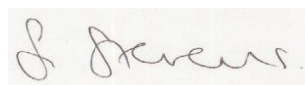
If you have any questions around this data sharing, please contact the Rare Disease Team at the NDRS (phe.ncardrsrd@nhs.net) or NHS England and Improvement (england.blueteq@nhs.net).

I would be grateful if you could cascade this information to relevant teams within your organisation to support the consistent adoption of the policy nationally.

With best wishes.

Yours sincerely,

Signed on behalf of Public Health England:



Sarah Stevens FFPH
Director
National Disease Registration Service

Signed on behalf of NHS England and Improvement:

A handwritten signature in black ink, appearing to read 'Nina Pinwill', is positioned above the printed name.

Nina Pinwill
Head of Commercial Operations, Commercial Medicines Directorate
NHS England and NHS Improvement

Cc Chief Executive
Chief Pharmacist
NHS England Commissioning Managers