**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**NICE indicator validity assessment**

# Assurance date: August 2023

Review date: August 2026

# Indicator IAP00610

# Adherence to nebulised therapy in Cystic Fibrosis

# (See also IAP00611 Normative adherence to nebulised therapy in Cystic Fibrosis for patients with chronic pseudomonas acquisition)

# Validity assessment

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| **Domain** | **Notes**  | **Assessment** |
| Importance | Indicator was designed to be produced using the CFHealthHub data platform (across all 26 adult Cystic Fibrosis centres) however public access to the data is currently unavailable.  | Data relating to the indicator is collected and managed by the CFHealthHub. |
| Evidence base | From indicator application form provided by NICE:“Cystic Fibrosis is an inherited life-limiting illness in which the commonest reason for premature death is respiratory failure due to uncontrolled lung infections. Cochrane systematic reviews, which summarise randomised controlled trial evidence, demonstrate the relationship between the process measure of daily treatment with inhaled mucolytics and antibiotics and the outcome of preserved lung health in terms of lung function improvement (FEV1) and reduced respiratory exacerbations (associated with decreased quality of life and loss of lung function which in turn is associated with reduced life expectancy (Cystic fibrosis: diagnosis and management NICE guideline [NG78] Published date: October 2017 ([https://www.nice.org.uk/guidance/ng78)](https://www.nice.org.uk/guidance/ng78%29)).People with Cystic Fibrosis (PWCF) find it difficult to establish sustained habits of self-care and median adherence to inhaled therapy in adults is less than 40% (Daniels et al Chest 2011; 140:425–432). Correspondingly, it can be difficult for clinicians to determine in an appointment whether worsening clinical symptoms are due to low adherence, or another medical reason such as an infection. CFHealthHub (CFHH) is a digital information technology platform that automatically collects adherence data, and makes time and date stamped data describing daily and weekly adherence to inhaled therapy (mucolytics and antibiotics) data available to PWCF and their clinical teams. This creates a learning health system that transforms CF care through behaviour change interventions that create clinician and patient activation. The data in CFHH has 3 purposes/audiences (hereafter referred to as ‘levels’);1) PWCF: There is considerable evidence (reviewed below) that making feedback of time and date stamped data about a desirable behaviour (taking medication) supports behaviour change (increased adherence). The CFHH enables ‘patient activation’ whereby patients have the knowledge, skills and motivation to contribute to the management of their own care.2) Clinician: Providing clinicians with accurate data on a PWCF’s adherence to their prescribed medication provides more complete information, which helps them interpret the clinical picture when a PWCF attends clinic. CFHH removes the invisibility of patient’s self-care behaviours and facilitates ‘clinician activation’ whereby clinicians are equipped with the knowledge, skills and motivation to support patients in building habits of self-care 3) Centre: Making the aggregate of this data available at a centre level will allow centre to track their performance over time, as well as centres with lower performance to seek support to improve adherence rates. This indicator is at the centre level, as it is this data which is made available beyond the PWCF and immediate clinical team, as well as used to compare the performance of CF centres. However, the PWCF and clinician level data sharing are the mechanism through which adherence improves, and therefore the rationale behind these will be provided throughout the form. It should be noted that the data being shared at the PWCF and clinician level is the same, though the purpose differs with the audience. Throughout the application form, it will be signposted when ambiguous which data level is being discussed.**Justification of adherence as a useful quality indicator in CF**The process measure of medication adherence has been favoured over an outcome measure of lung function, as there are insufficient numbers of patients at UK CF centres to detect a statistically significant change of 5% difference in lung function between centres (Nightingale & Osmond JCF 2017). There is strong randomised controlled trials (RCT) evidence for the relationship between the process measure of adherence to inhaled therapies and outcomes such as lung function and exacerbations. As such, this indicator is well placed to support quality measurement in CF.” | Evidence base exists for treatment of Cystic Fibrosis. This indicator aligns with NICE guidance:* NG78 - Cystic fibrosis: diagnosis and management, Published 25 October 2017, <https://www.nice.org.uk/guidance/ng78>
* QS168 - Cystic fibrosis, Published 18 May 2018, <https://www.nice.org.uk/guidance/qs168>

Evidence exists from RCTs which demonstrate the relationship between the use of inhaled therapies and the outcomes of lung function, exacerbation and quality of life (as outlined in the original application), including:[Self-management intervention to reduce pulmonary exacerbations by supporting treatment adherence in adults with cystic fibrosis: a randomised controlled trial | Thorax (bmj.com)](https://thorax.bmj.com/content/77/5/461)  |
| Specification  | Numerator: Number of doses (of inhaled therapy: antibiotics and mucolytics) taken in a day (per PWCF) is found from CFHealthHub inhalation data. This is capped at 100% based on the PWCF prescription. Adjusted for nebulised antibiotics require multiple accentuations for a complete dose.Denominator: Prescription (number of doses) per day as defined within CFHealthHub.Exclusions: People with lung transplants, as identified from the CF registry.Methodology: % adherence (of individual patients).A centre median based over an identified time period is calculated from individual patient % daily adherence.Geography: Cystic Fibrosis Centres.Data Source: CFHealthHubDisclosure control: Unknown, no data published at this stage | The indicator has defined components necessary to construct the indicator. |
| Feasibility  | All data from one source (CFHealthHub) and source supports the indicator, however at this stage not all CF Centres are providing data. | Data source relatively new however is designed to support the indicator. |
| Acceptability | Monitoring of indicator can take place in real time, however no data currently available to assess. Indicator is designed to reduce unscheduled care costs such as escalation to other medicines or avoidable admissions. | The indicator assesses performance that is attributable to or within the control of the audience. |
| Risk | Several limitations are identified in the initial indicator application, which include:* Potential technical limitations of the system including data loss and issues around timing for the ‘daily’ prescription
* Patients taking dry powders are missed by the system
* Methods by which patients could be moved out of the scope of this indicator
* Centres potentially reducing a patients prescription to increase adherence, hence the importance of considering alongside IAP00611 which has a normative prescription as a denominator

Additionally the initial assessment from IGB rated three criteria (Data; Presentation and Interpretation; Risks and Usefulness) as ‘Use with caution = data quality issue’ due to the fact only 3 centres had begun collecting and no data was available. This caution still applies.A related Prescribed Services [CQUIN indicator](https://www.england.nhs.uk/wp-content/uploads/2016/11/im2-cystic-fibrosis-patient-adherence.pdf) referred to as part of the application is no longer part of the CQUIN scheme.Data used to construct this indicator is not currently publicly available, therefore no assessment of results has taken place.Developments in CF treatment are continuing with CFTR modulators becoming more widely used, however adherence to nebulised therapy remains an important measure, particularly in those patients unsuitable for CFTR modulators (Allen, L., Allen, L., Carr, S.B. *et al.* Future therapies for cystic fibrosis. *Nat Commun* **14**, 693 (2023)).  | Limitations identified in the initial application remain unresolved as indicator data has yet to published.Treatment landscape continues to develop and this should be assessed at each indicator renewal. |

**Summary:** Indicator to be renewed.