1. **Treatment & Condition**

Pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282).

2. **Associated appraisal body & Summary of ruling**

NICE Technology Appraisal guidance TA504 (February 2018)

Pirfenidone is recommended as an option for treating idiopathic pulmonary fibrosis in adults only if:

- the person has a forced vital capacity (FVC) between 50% and 80% predicted
- the company provides pirfenidone with the discount agreed in the patient access scheme and
- treatment is stopped if there is evidence of disease progression (an absolute decline of 10% or more in predicted FVC within any 12-month period).

3. **Number of people in Northern Ireland expected to take up service/therapy**

Epidemiological data indicate that 500 people living with IPF in Northern Ireland fulfil the treatment criteria at any given time. Not all of these can be identified in a timely manner because of limited clinical service capacity. Pirfenidone being less well tolerated than the more recently introduced Nintadenib, more patients are thought to be currently on Nintadenib than on Pirfendone.

4. **Patient Access Scheme Availability**

(Yes/No)

The manufacturer of this product has agreed a patient access scheme which makes the product available with a discount. The size of the discount is commercial in confidence.

5. **Infrastructure Requirements**

The annual cost of pirfenidone is £26,171.72 per patient per year, assuming no wastage.

The manufacturer of this product has agreed a patient access scheme which makes the product available with a discount. The size of the discount is commercial in confidence.

This TA does not contain any material changes compared with its predecessor TA 268. Therefore, no significant change to current practice or existing costs is expected.
6. **Expected implementation period**
   
   There is no impediment to immediate implementation for new patients.

7. **Commissioning arrangements**
   
   This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis.

8. **Monitoring arrangements**
   
   The Respiratory Forum is currently seeking to establish monitoring arrangements for specialist respiratory drugs including pirfendone and nintadenib. It is also seeking funding to establish an Interstitial Lung Disease Northern Ireland Network and service model that would allow earlier and more comprehensive identification of IPF patients fulfilling treatment criteria and should lead to an increase in the utilisation of such treatments including pirfendone.

9. **DoH (NI) Legislative/Policy Caveats**
   
   This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.