

By email:

Ms Sarah Ellson
Field Fisher
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3 July 2017

Dear Ms Ellson

Appeal against Final Appraisal Determination (FAD): Pirfenidone for treating idiopathic pulmonary fibrosis (Review of TA 282) dated June 2017

Thank you for your letter of 23 June 2017 addressed to Andy McKeon and lodging an appeal on behalf of Roche Products Limited against the above FAD. I have taken over from Mr McKeon as vice chair with responsibility for appeals.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- 1(a) NICE has failed to act fairly,¹ or
- 1(b) NICE has exceeded powers;²
- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

Initial View

Ground 1 (a)

Ground 1.1(a) In determining that there was a relevant distinction between the subgroup of patients with a FVC between 50-80% and the total population (para 4.19 FAD) the committee acted contrary to policy and procedures with inadequate reasons and unfairly.

¹ formerly ground 1

² Formerly ground 3

A valid appeal ground.

Ground 1.2(a) NICE has directed itself that it is free to disregard the appeal panel's decision, which is fundamentally unfair and frustrates the appellants right of appeal.

A valid appeal ground.

Ground 1.3(a) the Appraisal Committee had a closed mind in respect of. and/or had predetermined to a significant degree, the recommendation which it made.

A valid appeal ground.

Ground 1(b)

Ground 1.1(b) The Guidance Executive and/or the Appraisal Committee acted outside their powers by disregarding the appeal panel's decision, thus frustrating the statutory appeal rights granted by regs 9 and 10 of the National Institute for Health and Care Excellence (Constitution and Functions) Regulations 2013

A valid appeal ground.

Ground 2

2.1 In determining that there was a relevant distinction between the subgroup of patients with a FVC between 50% and 80% and the total; population (para 4.19 FAD) the committee drew a distinction with no rational basis

A valid appeal point.

As I agree that all of your appeal points are valid they will be passed to an appeal panel for consideration and there is no need for further correspondence at this stage of the appeal process.

There will be an oral hearing. NICE will contact you to make arrangements.

Yours sincerely

Dr Rosie Benneyworth
Vice Chair
National Institute for Health and Care Excellence