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Evidence Review Group Report commissioned by the NIHR Evidence Synthesis Programme on behalf of NICE

Apalutamide for treating prostate cancer [ID1534]

ERG confidential addendum: Results with revised Patient Access Scheme discount for apalutamide following company's response to the consultation on the appraisal consultation document

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Commercial in confidence information for apalutamide is shaded in [redacted]. Commercial in confidence information for subsequent treatments modelled is shaded in [redacted].

1 Introduction

This document was developed on request from NICE as a result of a proposed increase in the Patient Access Scheme (PAS) discount for apalutamide following the company's response to the consultation on the appraisal consultation document that was received by the ERG on 14th June 2021. The company submitted to NICE a revised model and a briefing document reporting the results of a set of cost-effectiveness analyses based on the updated confidential PAS discount for the price of apalutamide (subject to approval) and updated assumptions to incorporate committee preferred assumptions and address residual uncertainties regarding metastatic hormone sensitive prostate cancer (mHSPC) patients who do not currently receive docetaxel in clinical practice.

The comparator treatment, androgen deprivation therapy (ADT) does not have a PAS discount, however, the subsequent line treatments modelled (in both the apalutamide and the ADT arms) have their own confidential PAS discounts. The company's revised cost-effectiveness results use the PAS prices for apalutamide and abiraterone (1L and 2L) and the list prices for the remaining subsequent treatments.

Table 1 shows the new proposed commercial in confidence PAS discount for apalutamide ([redacted]) and the confidential PAS discounts used for the subsequent treatments included in the company's economic evaluation. This document reproduces the tables of the company's revised base cases presented in the appraisal consultation document (Tables 3-8) using the new proposed apalutamide PAS discount and the PAS discounts for subsequent treatments.

Table 1 Drug costs with confidential PAS discounts

Treatment	List price per pack	PAS discount	Cost per model cycle
Apalutamide	112 x 60mg, £2,735.00	[redacted]	[redacted]
Abiraterone (1L)	56 x 500mg, £2,735.00	[redacted]	[redacted]
Abiraterone (2L)	56 x 500mg, £2,735.00	[redacted]	[redacted]
Enzalutamide	112 x 40mg, £2,734.67	[redacted]	[redacted]

Cabazitaxel	1 x 60mg, £3,696.00	[redacted]	[redacted]
Radium-223	1 x 6ml, £4,040.00	[redacted]	[redacted]

1L = First line; 2L = Second line

2 Company's revised base case

The company's revised base case includes all the committee preferred assumptions, which are in line with the ERG preferred assumptions as for the technical engagement. The results using PAS prices are shown in Table 2 for non-metastatic hormone relapsed prostate cancer (nmHRPC) and Table 3 for mHSPC.

The ICER for apalutamide plus ADT versus ADT alone is [redacted] per QALY for nmHRPC. For mHSPC, the ICER is [redacted] per QALY for apalutamide plus ADT versus ADT alone and [redacted] per QALY for apalutamide plus ADT versus docetaxel plus ADT.

Table 2 Company's revised base case results for nmHRPC (discounted, PAS prices)

Technologies	Total costs (£)	Total QALYs	Incr costs (£)	Incr QALYs	ICER (£/QALY)
ADT alone	[redacted]	3.60			
Apalutamide plus ADT	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
ADT: androgen deprivation therapy; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years.					

Table 3 Company's revised base case results for mHSPC (discounted, PAS prices)

Technologies	Total costs (£)	Total QALYs	Incr costs (£)	Incr QALYs	ICER (£/QALY)	ICER (£/ QALY): APA vs. ADT
ADT alone	[redacted]	[redacted]				
Docetaxel plus ADT	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Apalutamide plus ADT	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
ADT: androgen deprivation therapy; APA: apalutamide plus ADT; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years.						

3 Scenario analyses

The company performed scenario analyses, exploring some of the uncertainties of the cost-effectiveness results of nmHRPC and mHSPC patients. Here we reproduce the tables presented in the appraisal consultation document using the PAS prices for all treatments (Table 4 to Table 6 below). The following scenarios were investigated for both indications:

- Unadjusted for novel therapy and cross-over.
- Adjusted only for novel therapy and not cross-over.
- Assume time on treatment equal to PFS.

For mHSPC, some additional scenarios were explored:

- Assume equal post-progression survival between apalutamide and ADT.
- Remove chemotherapy as a subsequent treatment in patients who are unsuitable for chemotherapy.
- Assume lower utility values in patients who are unsuitable for chemotherapy (decrement of 0.1).

For patients not receiving docetaxel, further analyses using data from relevant subgroups within TITAN were conducted:

- Metastasis stage at diagnosis of M0 (non-metastatic)
- Low volume disease
- Unsuitable due to fitness/co-morbidity
    - Patients with a baseline ECOG score of 1
    - Patients over the age of 75
    - Patients with a baseline ECOG score of 1 who are over 75 years old.

Table 4 Company's scenario analyses for nmHRPC (discounted, PAS prices)

Scenarios	ICER (£/QALY) vs. ADT
Unadjusted	[redacted]
Adjusted only for novel therapy and not cross-over	[redacted]
Time on treatment equal to PFS	[redacted]
ADT: androgen deprivation therapy; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years.	

Table 5 Company's scenario analyses for mHSPC (discounted, PAS prices)

Scenarios	ICER (£/QALY) vs. ADT	ICER (£/QALY) vs. DOX
Unadjusted	[redacted]	[redacted]
Adjusted only for novel therapy and not cross-over	[redacted]	[redacted]
Time on treatment equal to PFS	[redacted]	[redacted]

Scenarios	ICER (£/QALY) vs. ADT	ICER (£/QALY) vs. DOX
Equal post progression survival	[redacted]	[redacted]
Remove chemotherapy as subsequent treatment	[redacted]	[redacted]
Reduce utility values by a decrement of 0.1	[redacted]	[redacted]
ADT: androgen deprivation therapy; DOX: docetaxel; ICER: incremental cost-effectiveness ratio; NA: not applicable; QALYs: quality-adjusted life years.		

Table 6 Company's subgroup analyses for mHSPC patients not receiving docetaxel (discounted, PAS prices)

Scenarios	ICER (£/QALY) vs. ADT
Full population	[redacted]
Metastasis stage at diagnosis of M0	[redacted]
Low volume disease	[redacted]
ECOG 1	[redacted]
Age >75	[redacted]
ECOG 1 & age >75	[redacted]
ADT: androgen deprivation therapy; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years.	