Prostate Cancer Pricing, Reimbursement, and Access

Description: Novel antiandrogens will need to present risk-sharing agreements in EU markets, while discussing contracting with US payers to ensure a competitive advantage. Vaccines suffer from inconclusive response measures and unattractive dosing.

This report addresses the following questions:

- How do access restrictions for prostate cancer drugs differ across markets and why?
- Which clinical trial comparators and outcomes are necessary for approval and uptake in each market?
- What impact, if any, will value assessment tools have on US reimbursement patterns?
- When and where are risk-sharing agreements useful in gaining market access?
- What are US and EU payers' and physicians' opinions on drugs targeting non-metastatic CRPC or metastatic HSPC?
- Which vaccines have a chance for uptake and reimbursement in US and EU markets?
- What does the future hold for radiotherapy Xofigo?

Contents:

EXECUTIVE SUMMARY

MARKET CONTEXT

- Marketed prostate cancer products in the US, Japan, and five major EU markets
- Pipeline prostate cancer treatments in late-stage development
- Bibliography.

GLOBAL PAYER AND KEY OPINION LEADER INSIGHTS

- Insights and strategic recommendations
- Payer archetypes and trends in access
- Non-metastatic castration-resistant prostate cancer
- Metastatic hormone-sensitive prostate cancer
- Evidence for the impact of earlier or combination treatment on overall resource use could gain traction with payers
- Patient-reported outcomes will become increasingly important, particularly for Xofigo
- Similar novel antiandrogens look to differentiate themselves from one another
- Providers grapple with whether or not combinations provide better long-term outcomes than sequential use of the drugs
- Advent of bundled payments will drive the need for data on optimal care pathways
- Novel immunotherapies and vaccines are welcomed alternatives, but will face similar challenges to Provenge
- Bibliography

US PRICING

- Pricing trends in the US look toward greater cost control
- Bibliography

US PAYER AND KEY OPINION LEADER INSIGHTS

- Insights and strategic recommendations
- Insurers commonly reimburse NCCN-backed indications; obtaining a category 1 recommendation will become increasingly important
- If efficacy and safety data are not differentiated from other drugs, twice-daily dosing may hinder BAY-1841788's potential
- Jevtana will be restricted to use after docetaxel, unless a substantial benefit is shown in FIRSTANA trial
- Prescribing patterns differ between medical oncologists and urologists; payers consider management of
CRPC by oncologists as ideal
- Cancer Drug Coverage Parity Act of 2
- could close gap in out-of-pocket costs between oral and inpatient drugs
- New drugs mean new opportunities for contracting
- Bibliography

US REIMBURSEMENT
- Insights and strategic recommendations
- NCCN guidelines reflect FDA labels
- NCCN Evidence Blocks
- Drug value frameworks will guide the formation of clinical pathways and reimbursement criteria in the future
- Payers have limited utilization management options despite rising costs, but oncology pathways are making inroads
- Branded prostate cancer therapies are generally found on top tiers as specialty drugs
- Prior authorization and step therapy criteria from numerous payers restrict the use of Xtandi
- Bibliography

JAPAN
- Price premiums are awarded for added benefit or innovation
- Pricing of launched prostate cancer treatments
- Bibliography

PRICING IN THE FIVE MAJOR EU MARKETS
- Insights and strategic recommendations
- ESMO drug ratings praise Xofigo, but are uncertain about Xtandi’s and Zytiga’s role before Docetaxel
- Jevtana restricted in many European countries due to poor benefit-to-risk ratio
- Xofigo is restricted to use after docetaxel therapy in most European countries
- Real-world data are a priority for assessment bodies
- Bibliography

FRANCE
- Insights and strategic recommendations
- ASMR rating has an impact on pricing
- The majority of new market entrants will be compared to Zytiga,
- While price is a concern, effective and tolerable vaccines will be a welcomed alternative
- Bibliography

GERMANY
- Insights and strategic recommendations
- Positive assessment from the G-BA will impact price negotiations
- Cell therapies will find entry into the German market at the hospital level through supplemental funding mechanisms
- Bibliography

ITALY
- Insights and strategic recommendations
- All established prostate cancer treatments are reimbursed by AIFA
- Regional health authorities perform thorough health technology assessments on new drugs
- Oral drugs subject to monitoring
- Bibliography

SPAIN
- Insights and strategic recommendations
- National reimbursement decisions are not a major access barrier in Spain
- Bibliography
- Regional restrictions tend to align with adverse event profiles and clinical trial exclusion Criteria
- Spanish Oncology Genitourinary Group recommendations
- Bibliography

UK

- Insights and strategic recommendations
- NICE and SMC assessments drive reimbursement decisions
- Cancer Drugs Fund
- Bibliography

APPENDIX

- Primary research
- Price assumptions
- Bibliography

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