Multiple Myeloma Pricing, Reimbursement, and Access

Description: Growth in the multiple myeloma market will be spurred by the approval of novel drugs and the increasing role of combination therapy, but risk-sharing agreements will be key to entry into increasingly restrictive markets.

This report addresses the following questions:

- How do access restrictions for multiple myeloma 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 monoclonal antibodies Darzalex and Empliciti?
- What effect will generic bortezomib have on the pricing and reimbursement of multiple myeloma drugs in the US and EU markets?

Contents:

EXECUTIVE SUMMARY

MARKET CONTEXT

- Novel therapies and combinations will increase the budget impact of multiple myeloma and the life expectancy of patients - spurring new restrictions and risk-sharing measures
- Marketed multiple myeloma products in the US, Japan, and five major EU markets
- Pipeline multiple myeloma treatments in late-stage development
- Bibliography

GLOBAL PAYER AND KEY OPINION LEADER INSIGHTS

- Insights and strategic recommendations
- Payer archetypes and trends in access
- Growing expenditure may trigger more restrictive access
- Endpoints and magnitude effect
- New drugs may fit into the growing role of maintenance therapy
- The impact of generic Velcade
- Bibliography

US PRICING

- Use of combination therapy and longer treatment durations pushing up costs in multiple Myeloma
- Monoclonal antibodies prove costly, but affordability increases with sustained responses
- 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 off-label and payer-restricted indications
- Oncologists: heightened restrictions unlikely for multiple myeloma medicines in near future
- Bibliography

US REIMBURSEMENT

- Insights and strategic recommendations
- NCCN guidelines heavily feature Revlimid, Thalomid, and Velcade
- 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
- Oral multiple myeloma therapies are found in the top tier of most commercial formularies and all Medicare formularies
- Prior authorization criteria follow FDA labels
- Revlimid dominates the multiple myeloma market, used in combination with most new agents
- Patient assistance programs look to improve access by relieving out-of-pocket costs, 28.Kyprolis gaining ground in earlier indications with enhanced efficacy
- Pomalyst is likely superior to Revlimid, but is set to be left for use in later lines of therapy
- New drugs must display superiority over future generic competition
- Numerous drugs are competing for use in relapsed and refractory disease

JAPAN

- Price premiums are awarded for added benefit or innovation
- Pricing of launched multiple myeloma treatments

PRICING IN THE FIVE MAJOR EU MARKETS

FIVE MAJOR EU MARKETS PAYER AND KEY OPINION LEADER INSIGHTS

- Insights and strategic recommendations
- Real-world data are a priority for assessment bodies
- Darzalex viewed as the more adaptable monoclonal antibody, but burden on hospitals could limit its potential
- Kyprolis is likely to become the standard of care for recurrent disease, but its high price may pose limitations
- Empliciti may face restrictions upon market entry
- The majority of multiple myeloma treatment is administered in an outpatient setting
- Ninlaro is an attractive oral option for elderly patients, reduces burden on ambulatory care
- Farydak will experience low usage due to poor risk-benefit ratio
- Pomalyst is reimbursed under a risk-sharing agreement in numerous European countries

FRANCE

- Insights and strategic recommendations
- ASMR rating has an impact on pricing
- Majority of Transparency Committee assessments in multiple myeloma gave ASMR level of III or better

GERMANY

- Insights and strategic recommendations
- Positive assessment from the G-BA will impact price negotiations
- No access barriers in Germany, but rising costs may trigger change

ITALY

- Insights and strategic recommendations
- All established multiple myeloma treatments are reimbursed in Italy
- Cost-sharing differs among older and newer drugs
- The majority of drugs are subject to monitoring

SPAIN

- Insights and strategic recommendations
- National reimbursement decision is not a major access barrier in Spain
- Pomalyst is recommended by the influential Spanish Myeloma Group in a new regimen
- Therapeutic positioning reports influence local and regional treatment guidelines
- Regional differences exist in drug reimbursement.
- Bibliography

UK

- Insights and strategic recommendations
- NICE and SMC decisions drive reimbursement decisions
- Four multiple myeloma medicines are reimbursed under risk-sharing, future entrants will need to offer discounts
- Cancer Drugs Fund
- Bibliography

APPENDIX

- Primary research
- Price assumptions
- Bibliography

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