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. 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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