Rheumatoid arthritis (RA) is a complex autoimmune condition characterized by chronic and progressive joint inflammation that may result in permanent, debilitating tissue damage. Early intervention with disease-modifying antirheumatic drugs (DMARDs), both conventional and biological, can effectively treat the symptoms of RA and slow joint destruction. However, high-cost biological therapy is typically initiated, with TNF-α inhibitors, in patients who have failed therapy with conventional DMARDs. The non-TNF-α inhibitor biologics (MabThera [Roche’s rituximab], Orencia [Bristol-Myers Squibb’s abatacept], RoActemra [Roche’s tocilizumab]) largely compete for use in the TNF-refractory population. The launch of biosimilar versions of Remicade (Janssen’s infliximab) in the EU5 markets in early 2015, and the anticipated arrival over the next few years of biosimilars for the leading RA biologics, Enbrel (Pfizer’s etanercept) and Humira (AbbVie’s adalimumab), will drastically change the dynamics in this high-priced market. In the increasingly crowded and intensely competitive RA market, emerging RA agents will face rigorous HTA and P&R negotiations as payers and physicians aim to balance clinical efficacy with budgetary constraints. This report analyzes European rheumatologists’ and payers’ expectations and attitudes regarding the changing RA market through year-end 2018.

Questions Answered in This Report:

- Impact of reimbursement and payer policies on the use of current RA biologics. How does reimbursement of RA biologics vary between the EU5 countries (France, Germany, Italy, Spain, and the United Kingdom)? What are the main reimbursement constraints for the newest RA biologics, and how do payers control and monitor prescribing in the different EU5 countries? What reimbursement factors (e.g., prescribing budgets, patient copays) impact rheumatologists’ prescribing the most? How will the prescribing of the new subcutaneous (SC) formulations of Orencia and RoActemra change between now and year-end 2018? How has the label extension of RoActemra approving the use in methotrexate-naive patients impacted physician prescribing or payer policies?

- Payer and physician perspectives on emerging agents for RA. How might evolving healthcare reforms and increasing cost-containment strategies affect reimbursement and uptake of novel agents for RA? What are the key market access considerations (e.g., clinical trial design, pharmacoeconomic data) relevant to pricing and of emerging RA agents in each country? What are the key market access challenges and levers in each country? How will Xeljanz (Pfizer’s
tofacitinib), the first oral kinase inhibitor for RA, fit into physicians’ treatment armamentarium for RA? Will it be used in DMARD-refractory or reserved for TNF-refractory RA patients? How will price factor into this agent’s use? Will oral delivery be a market access lever in the absence of improved efficacy compared to marketed biologics?

- Biosimilar infliximab (Celltrion’s Inflectra/Hospira’s Remsima), the first EMA-approved biosimilar of a monoclonal antibody, launched in the EU5 in early 2015, which will be followed by the launches of biosimilar etanercept (Pfizer’s Enbrel) and rituximab (Roche’s MabThera) in 2016 and biosimilar adalimumab (AbbVie’s Humira) in 2018. Will payers require use of the biosimilars in newly treated patients? Will they encourage switching patients currently on the brand to biosimilars? Will pharmacy-level switching be mandated? What are physicians’ (prescribers’ and non-prescribers’) attitudes toward biosimilars for RA? What are physicians’ expectations for prescribing of biosimilars, by line of therapy, by year-end 2018?

Scope:
Markets covered: France, Germany, Italy, Spain, and United Kingdom.

Primary research: We surveyed 255 European rheumatologists and conducted 15 country-specific interviews with European payers.

- France: Former HAS (Commission de la Transparence) member; hospital formulary committee member, Lyon; hospital formulary committee member, Strasbourg.

- Germany: Honorary chair of a regional Physicians’ Association/ex-chairman of a regional association of physicians/G-BA advisory role, Dusseldorf; member of a Physicians’ Association, Hessen; head of drugs of sickness fund, Dusseldorf.

- Italy: Prontuario terapeutico ospedaliero (PTO) and prontuario terapeutico ospedaliero regionale (PTOR) member/chief hospital pharmacist, Rome; PTO/PTOR advisor/ hospital/regional pharmacy director, Palermo; PTO/PTOR member/hospital/regional formulary committee member/hospital/regional pharmacy directors, Trieste-North Italy.

- Spain: Hospital/regional formulary committee member/hospital pharmacy director, Valencia; hospital/regional formulary committee member/hospital pharmacy director, Barcelona; hospital/regional formulary committee member/hospital/regional pharmacy director, Madrid.

- United Kingdom: CCG member/hospital formulary committee member, London; CCG member/hospital formulary committee member, Sunderland; CCG member/hospital formulary committee member, Brighton.

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