Crohn’s Disease and Ulcerative Colitis (Market Access Landscape) | Physician & Payer Forum | EU5 | 2015

Moderate to severe inflammatory bowel disease (IBD) patients who fail to respond to conventional treatments, such as aminosalicylates, corticosteroids, and immunosuppressants, are commonly treated with biologic therapies. Until recently, TNF-alpha inhibitors Remicade (infliximab; Merck) and Humira (adalimumab; AbbVie) were the only biologics approved for Crohn’s disease (CD) and ulcerative colitis (UC) in Europe. Another, Simponi (Merck), was approved by the EMA for UC in 2013. In 2014, a CAM inhibitor, Entyvio (vedolizumab; Takeda), became the first non-TNF-alpha biologic granted European marketing authorization for CD and UC. The first biosimilars in the IBD field, Inflectra (infliximab; Hospira) and Remsima (infliximab; Celtrion), received marketing authorization from the EMA in 2013 and were subsequently launched in EU5 countries in the beginning of 2015. Despite the recent launches, Remicade and Humira still dominate the EU5 IBD market. However, the dynamics of this high-priced market are about to change with the introduction of the less expensive biosimilar versions of infliximab and adalimumab (launch expected 2018). In addition, new biologics Stelara (Janssen) for CD and Xeljanz (Pfizer) for UC are expected to become approved in Europe in 2016. This report analyzes European physicians’ and payers’ attitudes with respect to the changing CD/UC market through year-end 2018. We focus on physicians’ and payers’ view of the marketed TNF-alpha inhibitors; recently launched Simponi and Entyvio, infliximab, and adalimumab biosimilars, and emerging therapies Stelara and Xeljanz.

Questions Answered in This Report:

- Impact of reimbursement and payer policies on use of current CD and UC biologics: What do prescribing patterns for biologics tell us about the impact of reimbursement and pricing policies for these therapies in CD and UC? What reimbursement factors (e.g., prescribing budgets, patient copays) impact gastroenterologists’ prescribing the most? Which biologic is the leading treatment of choice for CD and UC in each EU5 country? How are recently launched Simponi and Entyvio used by EU5 gastroenterologists? How do healthcare authorities monitor prescribing? How could regional discounts and risk-sharing agreements improve market penetration of the current CD/UC biologics?

- Payer and physician perspectives on emerging agents for CD and UC: How might evolving healthcare reforms and increasing cost-containment strategies affect reimbursement and uptake of novel agents for CD and UC? How important are pharmacoeconomic data for
reimbursement and pricing decisions? What are the key market access challenges in each country? Do gastroenterologists differ from payers in their prioritization of attributes emerging therapies must demonstrate in order to challenge the positioning of the TNF-alpha inhibitors? What price point for an emerging agent is acceptable for reimbursement before TNF-alpha inhibitors? What is payers’ opinion on the importance of conducting head-to-head studies? Will the more convenient route of administration be a market access lever? How could patient access schemes and regional discounts improve market access for the emerging biologics? How will use of recently launched and emerging agents impact prescribing of TNF-alpha inhibitors by the end of 2018?

- The effect on market dynamics of the launch of infliximab biosimilars: Will payers require use of the biosimilars in newly treated patients? Will they encourage switching? What are physicians’ attitudes toward biosimilars for IBD? Will pharmacy-level switching be allowed? What are physicians’ expectations for biosimilar uptake by year-end 2018? What are payers’ expectations?

Scope:

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

Primary research: surveys of 253 gastroenterologists and 15 payers, all of whom have influence at a national or regional level. Interviewed payers include the following:

- France: ex HAS’s Commission de la Transparence member, member of the French National Guideline Committee; regional formulary committee member, pharmacy director, advisor to the HAS; HAS consultant.

- Germany: head of drug division at Association of Statutory Health Insurance, G-BA member; head of drug division at an insurance fund; member of National Associations of Statutory Health Insurance, G-BA member.

- Italy: Prontuario terapeutico ospedaliero (PTO) and prontuario terapeutico ospedaliero regionale (PTOR) member; advisor to AIFA and PTO/PTOR member; AIFA advisor and PTO/PTOR member.

- Spain: member of Genesis group (group for innovation, assessment, standardization and research in the selection of drugs, of the Spanish Society of Hospital Pharmacists); regional and hospital formulary committee member, hospital pharmacy director; member of Pharmacy Therapeutics Committee of MHDA (hospital medicines of ambulatory dispensation), member of pharmacy and therapeutics committee, hospital pharmacy director.

- United Kingdom: CCG member, hospital formulary committee member, head of medicines managements of a large NHS trust, member of a CCG formulary committee, member of CCG Medicines Management Committee; CCG member, hospital pharmacy director, associate chief pharmacist for a CCG, CCG commissioner; hospital pharmacy director, formulary committee member, member of Medicine Management Committee.
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