Inspiring and Engaging Employers to Action

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What's New in Specialty Pharmacy?

- Every new drug is now a specialty drug! Does it make sense to keep this category separate?
- Undefined beyond price
- Specialty drugs are over 53% of drug spend – aren't they just brands?
- Progress is being made in the following diseases:
  - Inflammatory bowel disease
  - Plaque psoriasis
  - Atopic Dermatitis
  - Alzheimer's
  - Hemophilia
  - Hereditary ATTR-Mediated Amyloidosis

Navitus' List of New Specialty Drugs

INFLAMMATORY BOWEL DISEASE

- Inflammatory bowel disease (IBD) = Crohn's disease and ulcerative colitis
- Some patients develop difficult-to-treat disease
- Treatments may be costly and not entirely effective
- IBD is consequently a top priority for specialty drug development

Navitus' List of New Specialty Drugs

Two currently available specialty medications are expected to expand to treat IBD

1. **Skyrizi™ (risankizumab)**
   - Subcutaneously injected IL-23 inhibitor
   - Currently used for treating plaque psoriasis
   - FDA decision for use in treating Crohn's disease expected in February 2022
   - Ongoing trials until 2024 for treating ulcerative colitis

Navitus' List of New Specialty Drugs

2. **Rinvoq® (upadacitinib)**
   - Ofal JAK inhibitor
   - Currently indicated for the treatment of rheumatoid arthritis
   - Awaiting a Q3 2022 FDA decision for use in treating ulcerative colitis
   - Phase 3 trials for treating Crohn's disease are ongoing

Additional biologics may be approved in 2023

- **mirikizumab** & **brazikizumab** (subcutaneously injected IL-23 inhibitor)
- **etrasimod** (oral S1P modulator)

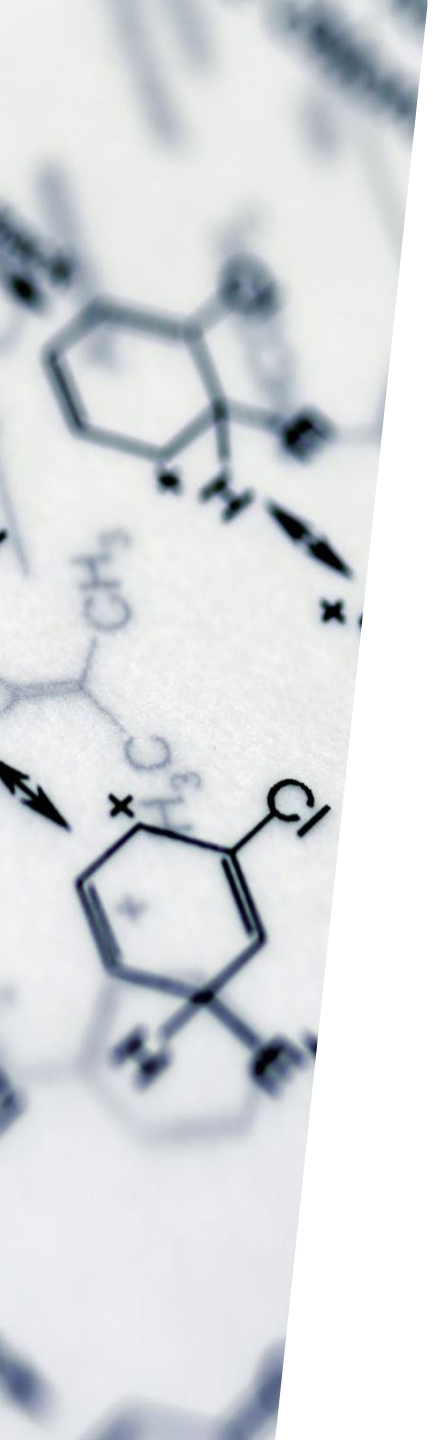
Navitus' List of New Specialty Drugs

PLAQUE PSORIASIS

- A chronic skin condition treated with high-cost biologics

New treatments

- **Bimekizumab**
  - Monthly subq injected IL-17F and IL-17A inhibitor
  - Superior results compared to Humira® (adalimumab), Stelara® (ustekinumab) and Cosentyx® (secukinumab)
  - FDA review of bimekizumab delayed by COVID-19 travel restrictions limiting manufacturing site inspections
  - A decision is likely to be delayed until at least early 2022



Navitus' List of New Specialty Drugs

PLAQUE PSORIASIS

New treatments

- **Deucravacitinib**
  - Oral tyrosine kinase 2 (TYK2) inhibitor
  - Closely related to JAK inhibition
  - Trials data for plaque psoriasis were submitted to the FDA by the end of 2021 for a potential 2022 approval
  - Early-phase trials for Crohn's disease, psoriatic arthritis, ulcerative colitis and systemic lupus erythematosus

Navitus' List of New Specialty Drugs

ATOPIC DERMATITIS

- Chronic skin disease
- Characterized primarily by skin lesions and intense itching
- Most patients are effectively treated with a variety of generic topical medications
- Some patients require systemic treatments
- Few advances have been made since the approval of Dupixent® (dupilumab) in early 2017
- This may change in late 2021 and 2022, as numerous specialty products are awaiting FDA approval

Navitus' List of New Specialty Drugs

ATOPIC DERMATITIS

Anticipated agents are oral JAK inhibitors

- **Rinvoq® (upadacitinib)**
- **Olumiant® (baricitinib)**
- **Abrocitinib,** a novel JAK inhibitor

All three agents were expected to be approved in 2021

Approvals were delayed by an FDA advisory committee meeting to discuss safety concerns for the entire drug class

It is unclear when the FDA may make decisions on all three pending applications

Navitus' List of New Specialty Drugs

ATOPIC DERMATITIS

- **Tralokinumab**
  - Subcutaneously injected IL-13 inhibitor
  - Expected in 2022
  - Has been studied in cases of moderate and severe disease
  - Requires injection either every two weeks or every four weeks
  - FDA rejected the 2021 application due to an issue with the injection device
  - A decision on the updated application is expected in 2022

Navitus' List of New Specialty Drugs

ALZHEIMER'S DISEASE

- **Aduhelm®** (**aducanumab**) made headlines throughout 2021 as the first of many biologic agents under investigation for the treatment of Alzheimer's disease
- **Lecanemab** and **donanemab**
  - Intravenously infused amyloid beta protein inhibitors
  - Intended to treat early-stage Alzheimer's disease
  - Received breakthrough therapy designation and have begun rolling data submissions to the FDA
  - One or both agents could receive accelerated approval in late 2022 or the FDA may wait until 2023 for more clinical data to become available for both products

Navitus' List of New Specialty Drugs

ALZHEIMER'S DISEASE

- **Gantenerumab**
  - Expected to be the first subcutaneously administered amyloid beta protein inhibitor
  - Submission to the FDA may not occur until the end of 2022 or later for a 2023 approval

Navitus' List of New Specialty Drugs

HEMOPHILIA

- Gene therapy is expected to represent a significant portion of specialty growth in the next decade
- Payers and society must grapple with the ramifications of paying upfront for one-time administrations that effectively "cure" chronic diseases
- Hemophilia is expected to play a significant role in development of gene therapy

Navitus' List of New Specialty Drugs

HEMOPHILIA

- **Roctavian (valactocogene roxaparvovec)**
  - The first-ever gene therapy treatment for hemophilia A
  - Could be approved by late 2022
  - Expected to cost $3 million for a one-time administration
  - Trials have demonstrated **reductions** in both bleeding episodes and the use of expensive prophylactic and on-demand treatments for five years and counting

Navitus' List of New Specialty Drugs

HEMOPHILIA

- **Etranacogene dezaparvovec**
  - The first gene therapy treatment for hemophilia B
  - Could receive accelerated approval in late 2022
- **Fidanacogene elaparvovec**, a competitor, is expected to have data available for potential approval in late 2023

Navitus' List of New Specialty Drugs

HEREDITARY ATTR-MEDIATED AMYLOIDOSIS

- FDA-designated orphan drugs are medications to treat rare diseases affecting 200,000 or fewer Americans
- Orphan drugs represent the majority of drugs approved in 2020 (53%) and the largest portion (47%) of the specialty pipeline

Navitus' List of New Specialty Drugs

HEREDITARY ATTR-MEDIATED AMYLOIDOSIS

- **Vutrisiran**
  - Subcutaneously-injected, small-interfering RNA inhibitor of transthyretin protein
  - Intended for use in hereditary transthyretin amyloidosis with polyneuropathy
  - Next-generation improvement of **Onpattro® (patisiran**)
  - Subq vs intravenous infusion
  - Extends the dosing interval from every three weeks to every three months

Specialty Drug Trend and Biosimilars

- Specialty drug prescription growth per member per month (PMPM):
  - 12.8% in 2019
  - 11.8% in 2020
  - 14.2% in 2021
- PMPM specialty drug cost has doubled from **$615** in 2016 to **$1,295** in 2021
- Average cost of specialty drug on the pharmacy benefit has increased from **$3,604** to **$4,562** between 2016 and 2021

Specialty Drug Trend and Biosimilars

- Biosimilars are expected to help reduce this trend
- Currently a handful of biosimilars in the market
- Unless these products are prioritized by plan sponsors, the long-term savings will not be realized
- **Plan sponsors continue to prioritize rebates, not drug price reduction**
- This short term strategy will likely have long term consequences if the biosimilar market does not gain momentum like it has in Europe

Biosimilars Can Reduce Specialty Drug Costs

- Reduced spend from biosimilars and specialty generics has been offset by a growth in the number of specialty drugs entering the market
- Biosimilar utilization has increased from 12.4% in 2020 to 22.5% in 2021: more meaningful impact expected as biosimilars for Humira enter the market
- Humira biosimilars have struggled to gain share: stumbled on pricing strategies at launch

Biosimilars Can Reduce Specialty Drug Costs

More established biosimilars

- Filgrastim biosimilars (Zarxio and Nivestym) are better established biosimilars
- They had the greatest market share in 2021 at **76.1%**
- Zarxio was the first biosimilar to enter the US market in 2015
- 5 biosimilars for trastuzumab on the market: market share increased from **1.5%** in 2019 to **68.6%** in 2021
- The first trastuzumab biosimilar to hit the market was Kanjinti: launched July 2019

Biosimilars Can Reduce Specialty Drug Costs

- Adalimumab (Humira) biosimilars
- 2 launched January 2023
- 7 currently approved
- More FDA approvals expected
- Savings expected in early 2023
- Full realization of savings will not be achieved until 2024

Biosimilars Can Reduce Specialty Drug Costs

Inflammatory (and auto-immune) conditions are the top category for spend

- Top 3 drugs by cost are:

1. Adalimumab/Humira
   - Average 2021 cost per prescription: **$6398**
   - Plan cost per member per year trend: **25.9%**
2. Ustekinumab/Stelara
3. Etanercept/Enbrel
   - 2 approved etanercept biosimilars that have been kept off the market due to patent litigation

Biosimilars Can Reduce Specialty Drug Costs

- The competitive market between innovator brands and biosimilars is more similar to brand-to-brand versus brand-to-generic competition
- Biosimilars may not be the lowest net cost therapy if the innovator brand is willing to offer rebates or price concessions

Biosimilars Can Reduce Specialty Drug Costs

- Of the drugs with biosimilars on the market for at least 2 years:
  - Infliximab biosimilars have the smallest market share – 22.6% in 2021, up from 10.0% in 2019
  - 4 infliximab biosimilars approved
  - 3 have launched in the United States
  - Inflectra was the second biosimilar approved in the US: 2016
  - Pfizer has withheld Ixifi from the US market to avoid competing with Inflectra
- As more biosimilars enter the market, average price per unit declined for all infliximab medications

Questions?