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Congressional and Regulatory Outlook Discussion

National Summit on Autoimmune Disease

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Current Issues Affecting Autoimmune Patients: Examples

- Access to Care: Assessing and Addressing Barriers
- Patient-Centered Care
 - Safety Considerations
 - Value Discussions
 - Patient Engagement Initiatives
- Impact of Benefit Designs and Payment Policies on Patient Access and Quality of Care
 - Premium, Deductible, and Copay/Coinsurance Structures
 - Coverage and Utilization Management Issues (e.g., Step Therapy, Prior Authorization, Formulary Restrictions)
 - Legislative and Regulatory Interplay
- Research Funding and Activities
 - Identifying the Community
 - Assessing and Quantifying the Burden/Impact of Autoimmune Disease
- Education and Public Awareness
- Additional Issues

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Access to Care: Assessing and Addressing Barriers

- Access issues for patients include the following, among others:
 - Availability, scope, and affordability of health insurance coverage
 - Copay/coinsurance policies
 - Benefit designs, including prescription drug formularies and tiering
 - Step therapy and fail-first restrictions
 - Prior authorization requirements
 - Narrow provider networks
- These issues arise in many contexts and under many different programs
 - Affordable Care Act (ACA) essential health benefits (EHB) requirements and nondiscrimination protections
 - Commercial/employer insurance market
 - Medicare
 - Medicaid

Access to Care: Assessing and Addressing Barriers

- Some key areas to watch:
 - ACA nondiscrimination regulations and guidance status
 - EHB-related policies
 - Ongoing implementation and rulemaking relevant to EHB policy
 - Plans subject to, and plans exempt from, EHB requirements
 - Medicare Part D
 - Formulary requirements, including protected classes and other policies
 - Information access issues, such as access to formularies and relevant, meaningful cost-sharing information
 - Considerations under recent rulemaking, guidance, enacted and potential legislation, and the President's proposed budget
 - Part D coverage gap (donut hole) policies and potential impact
 - True out-of-pocket costs (TrOOP) issues
 - Rebate and discount pass-through policies
 - Impact on, and influence from, commercial/employer market
 - Medicaid
 - Fate of ACA expansion provisions
 - Eligibility issues, coverage standards, and formulary requirements
 - State waivers: work requirements, requests for formulary restrictions
 - CMS Innovation Center Models/Demonstrations

Patient-Centered Care

- Safety Considerations
 - Examples: Biosimilars Naming, Labeling, and Interchangeability Issues; Non-Medical Switching Policies
- Impact of Payment Policies on Patient Access
 - Examples: Biosimilars Payment Issues; Influence of Reimbursement on Coverage and Availability of Items and Services; Medicare Part D Patient Out-of-Pocket Cost Issues; (Withdrawn) Medicare Part B Drug Payment Model Proposal
- Value Discussions
 - Examples: Institute of Clinical and Economic Review (ICER) and Other Value-Assessment Models, Frameworks, and Reviews; Government and Other Payers' Interest in Value-Based Pricing and Purchasing
- Patient Engagement Initiatives
 - Examples: FDA Patient Engagement Initiatives; ICER Comment Opportunities; Proposed Rules from Federal and State Agencies; State and Federal Legislation

Impact of Benefit Designs and Payment Policies on Patient Access and Quality of Care

- Premium, Deductible, and Copay/Coinsurance Structures
 - Insurance offerings and implications for patients and the system
 - E.g., High-deductible health plans, association health plans, short-term limited duration plans
 - Potential changes to EHB and/or health care nondiscrimination rules/guidance
- Coverage and Utilization Management Issues
 - Step therapy and fail-first restrictions
 - Prior authorization requirements
 - Formulary design issues
- Legislative and Regulatory Interplay
 - ACA and subsequent legislation (e.g., budget/appropriations bills, 21st Century Cures, user fee and other reauthorization bills, market stabilization package, etc.)
 - Medicare and Medicaid statutory provisions and regulations
 - CMS Innovation Center Request for Information, guidance, and models/demonstrations
 - State laws, regulations, guidance, and initiatives
 - Private insurance market

Research Funding and Activities

- Key goals
 - Identifying the community
 - Assessing and quantifying the burden and impact of autoimmune disease
 - Learning more about the mechanism(s) of action involved in autoimmune disease
 - Developing best practices for diagnosis and clinical pathways and guidelines for treatment
 - Researching and developing new and improved treatments for patients
- National Institutes of Health (NIH) activities
 - NIH Autoimmune Diseases Coordinating Committee
 - National Institute of Allergy and Infectious Diseases (NIAID)
 - National Institute of Environmental Health Sciences (NIEHS)
- Patient-Centered Outcomes Research Institute (PCORI) research grants
- Potential public and private partnerships for autoimmune research
- Legislative appropriations and other potential funding sources
- Autoimmune disease registry

Education and Public Awareness


- Physician/patient education & “time to diagnosis” issues
 - Needs for additional physician education and other public awareness initiatives
 - “Time to diagnosis” (and/or incorrect diagnosis) remains a major barrier to appropriate treatment for individuals with autoimmune diseases
- Possible initiatives:
 - Increased medical school programming focused on autoimmune diseases
 - Continuing Medical Education programs on autoimmune diseases
 - Patient and provider outreach and education programs
 - Engagement with federal- and state-level policymakers
 - Public awareness initiatives
 - Media campaigns
 - Autoimmune walks and other events
 - Social media presence
 - Autoimmune Disease Awareness Month
 - Autoimmune Institute – to be discussed in a later session

Potential/Proposed Legislation and Regulations To Watch

- 21st Century Cures Act: Ongoing Implementation
- Budget and Appropriations Bills
- Market Stabilization Legislation
- Patients' Access to Treatment Act (PATA)
- User Fees Reauthorization Bills
- 340B Drug Pricing Program Reforms (possible legislative reform; pending rulemaking and guidance)
- Bills Addressing State Pharmacy “Gag Laws” (e.g., Patient Right to Know Drug Prices Act; Know the Lowest Price Act)
- Pending and Possible Future Medicare Part D Rules
- Possible Part B Reforms or Demonstrations; Annual Part B Payment Rules
- Annual Notice of Benefit and Payment Parameters Rules and Guidance
- Potential/Proposed Legislation and Regulatory Actions Regarding Right-to-Try Policies, Opioids, Drug Pricing, Nondiscrimination, Etc.
- And be sure to keep an eye on state actions and initiatives, as well

Questions/Discussion

Thank You!



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