

Overcoming Hurdles

Insurance, Scripts, and Specialty Pharmacy





INTRODUCING...



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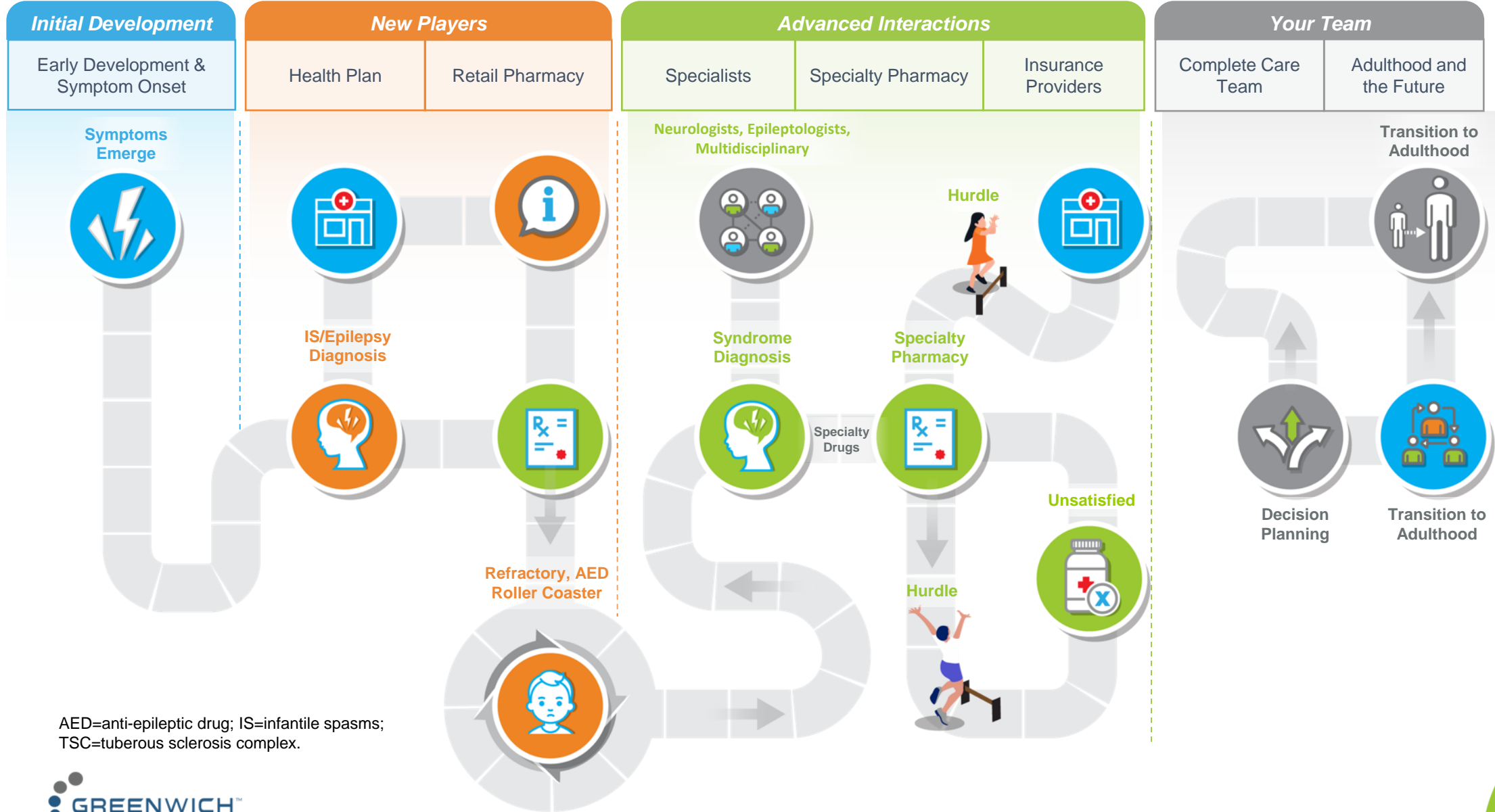
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Potential Hurdles in the TSC Journey



AED=anti-epileptic drug; IS=infantile spasms; TSC=tuberous sclerosis complex.

Potential Hurdles in the TSC Journey



Initial Development

Early Development & Symptom Onset

Symptoms Emerge



New Players

Health Plan

Retail Pharmacy

Advanced Interactions

Specialists

Specialty Pharmacy

Insurance Providers

Your Team

Complete Care Team

Adulthood and the Future

TSC symptoms show up differently in every individual with TSC resulting in many drug therapies



Brain

- Anti-epileptic drugs (AEDs) for seizures¹
- Immunotherapies (mTOR)^{2,3}



Skin

- Topical treatments for skin conditions⁵



Kidneys

- Blood pressure agents⁴
- Low-protein diets⁴
- Immunotherapies (mTOR)^{2,3}



Lungs

- Immunotherapies for lung disease⁶



Heart

- Agents that reduce fluid buildup⁷
- Blood pressure agents⁷

mTOR=mechanistic target of rapamycin.

Potential Hurdles in the TSC Journey





Common Jargon

Cost Sharing

Deductible	The amount of money you must pay before insurance will pay a claim ¹
Co-insurance	Your share against a claim ²
Copay	The amount you owe after insurance has paid ³
Out of pocket	Money paid from your reserves ⁴
Out of network	An HCP that doesn't have a contract with your health plan to provide service ⁴

Health Care Services

Pharmacy Benefit Manager (PBM)	A third-party organization that administers prescription drug benefits on behalf of health plans ⁵
Health plan	A type of insurance coverage that pays for medical and surgical expenses incurred by the insured ⁴
Vertical integration	The combination of two or more stages of production normally operated by separate firms, such as when health plans acquire pharmacy benefit managers or specialty pharmacies ⁶
Specialist consult	A conversation with a doctor that specializes in a disease or body system, such as a neurologist ⁴
Genetic testing	Type of medical test that identifies changes in chromosomes, genes, or proteins and can confirm or rule out suspected genetic conditions ⁷

Pharmacy

Formulary & Tier	A formulary is a list of prescription drugs covered by your health plan ⁴ A tier a category within the formulary (usually by drug type) that further divides drugs by cost ⁴
Electronic Rx	A prescription entered into a computer that is automatically sent to a pharmacy ⁸
Side effects	An unwanted effect from a drug that comes along with the intended effect ⁴

References: 1. HealthCare.gov. Deductible. Accessed January 12, 2021. <https://www.healthcare.gov/glossary/deductible/> 2. HealthCare.gov. Coinsurance. Accessed January 12, 2021. <https://www.healthcare.gov/glossary/co-insurance/> 3. HealthCare.gov. Copayment. Accessed January 12, 2021. <https://www.healthcare.gov/glossary/co-payment/> 4. Centers for Medicare and Medicaid Services. Updated May 14, 2006. Accessed January 12, 2021. <https://www.cms.gov/apps/glossary/default.asp?Letter=O&Language=English> 5. The Commonwealth Fund. April 22, 2019. Accessed January 12, 2021. <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> 6. Hanna J. Accessed January 26, 2021. <https://www.pharmacytimes.com/news/vertical-integration-in-health-care-the-next-stairway-to-heaven> 7. National Library of Medicine. MedlinePlus Genetics. Accessed January 12, 2021. <https://medlineplus.gov/download/genetics/understanding/testing.pdf> 8. HealthIT.gov. Updated September 10, 2019. Accessed January 12, 2021. <https://www.healthit.gov/faq/what-electronic-prescribing>

Integrated Payer Organizations

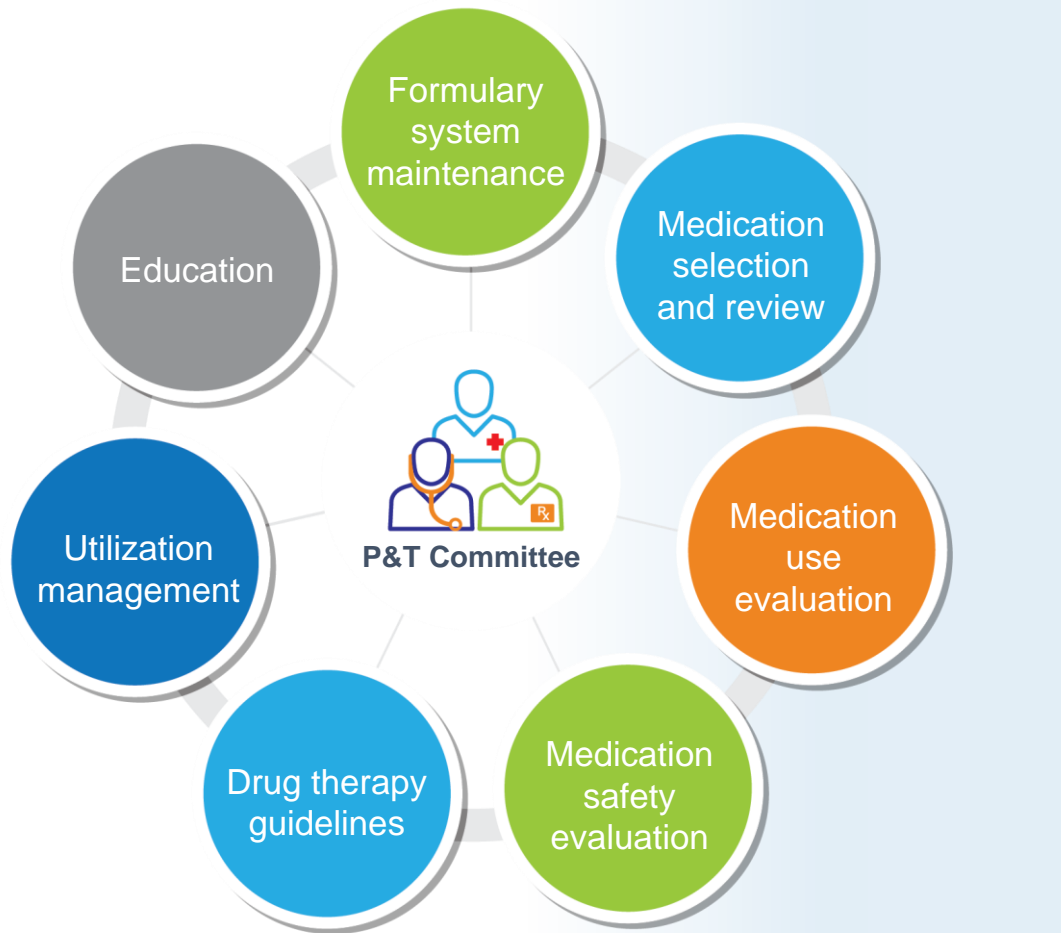
All 4 of the top specialty pharmacies are fully or partially owned by one of the largest PBMs and vertically integrated into large organizations



	UnitedHealthcare	aetna	Cigna	Anthem	Humana	BlueCross BlueShield
Insurer	UnitedHealthcare A UnitedHealth Group Company	aetna SM	Cigna	Anthem	Humana	BlueCross BlueShield
PBM	OPTUMRx	CVS caremark	EXPRESS SCRIPTS	ingenioRx	Humana Pharmacy Solutions	PRIME THERAPEUTICS
Specialty Pharmacy	briova _{Rx}	CVS specialty	accredo	CVS specialty	Humana Pharmacy	allianceRx <i>Walgreens + PRIME</i>
Provider Services	OPTUM Care	CVS minute clinic Health HUB	Cigna Collaborative Care	CareMore HEALTH Aspire Health	Partners in Primary Care CONVIVA Care Center Kindred Healthcare	

Who Makes Coverage Decisions?

Pharmacy & Therapeutics (P&T) Committee responsibilities



P&T Committee is made up of:

- Physicians (Medical Directors)
- Pharmacists
- Nurses

Representing specialties such as:

- Immunology
- Oncology
- Dermatology
- Infectious disease
- Neurology

Committee determines

- Formulary
- Utilization management criteria
- Meet several times annually
- Decisions are then taken downstream to health plans, employer groups, and members



How Are Decisions Made?



Clinical Data

- FDA label
- Published data
- Clinical guidelines
- Key opinion leaders



Financial

- Burden of illness
- Unit cost
- Discounts and rebates



Management

- Specialty
- Tier
- Utilization management

FDA=US Food and Drug Administration.



Utilization Management Types

Prior Authorization (PA)	Approval from a health plan that may be required before a service or prescription is covered by a health plan ¹
Step Therapy	Type of prior authorization that requires use of the most preferred drug therapy before allowing other therapies ²
Quantity Limit	Limit on the amount of a drug per duration of time (eg, 30 pills per 30 days) ³
Medical Policy	A set of guidelines or requirements that need to be met for medical services, procedures, devices, and drugs before coverage is provided ⁴

General Individual Cost Share^{5,6}

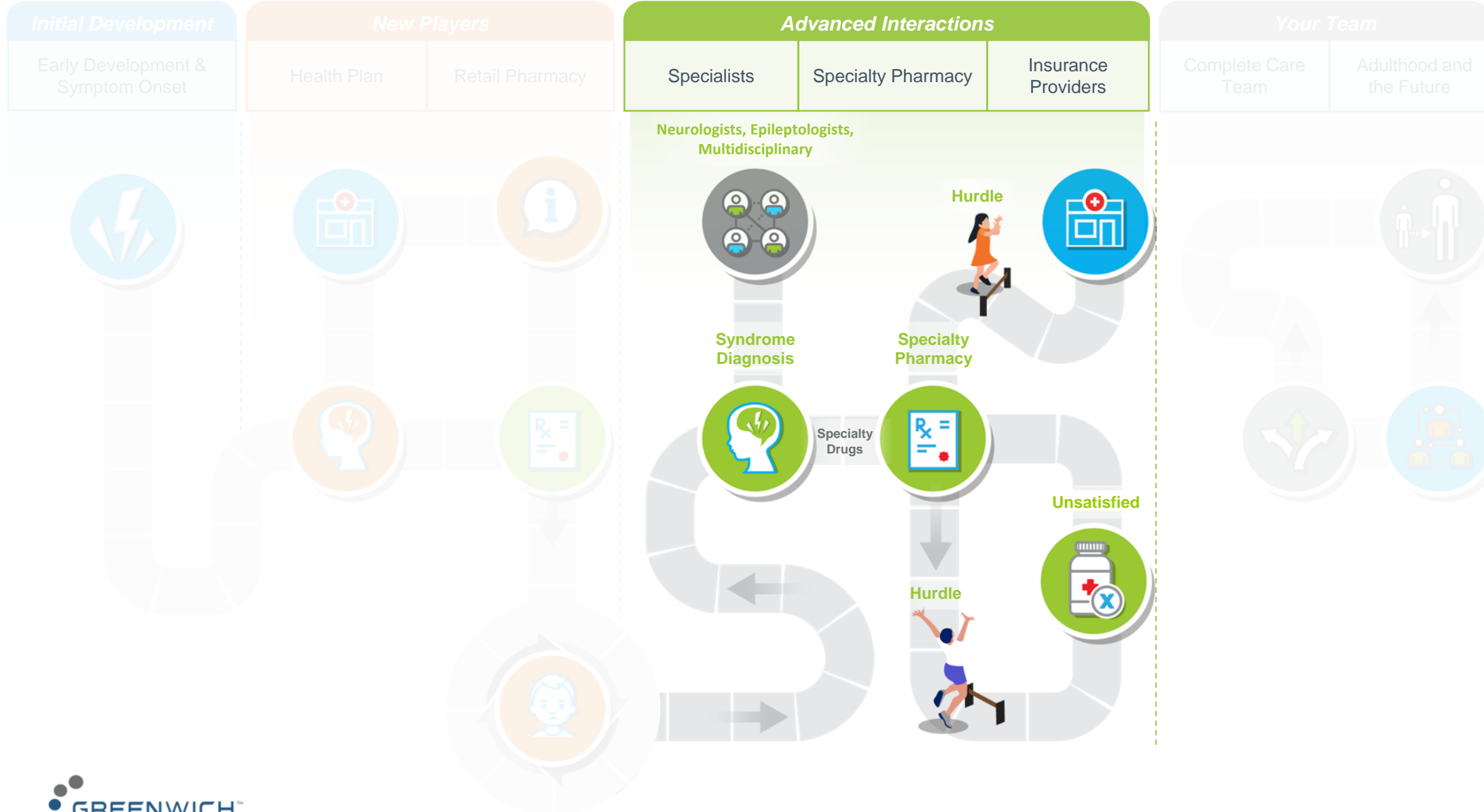
Tier 1	Prescription drug tier with the lowest cost tier of prescription drugs, majority are generic
Tier 2	Prescription drug tier with medium-cost drugs, most are generic with some brand-name drugs
Tier 3	Prescription drug tier with higher-cost drugs, the majority are brand-name drugs and some are specialty drugs
Tier 4 or Specialty	Prescription drug tier with the highest-cost drugs, majority are specialty drugs

References: 1. HealthCare.gov. Prior authorization. Accessed January 12, 2021. <https://www.healthcare.gov/glossary/prior-authorization/> 2. Centers for Medicare and Medicaid Services. August 7, 2018. Accessed January 12, 2021. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs> 3. Medicare Interactive.org. Accessed January 12, 2021. <https://www.medicareinteractive.org/glossary/quantity-limit> 4. Wellmark. Accessed January 12, 2021. <https://www.wellmark.com/Provider/MedPoliciesAndAuthorizations/MedicalPolicies/MedicalPolicies.aspx> 5. Blue Cross Blue Shield of North Carolina. 2021. Accessed January 12, 2021. <https://www.bluecrossnc.com/understanding-insurance/how-drug-benefits-work/copayment-tier-definitions#:~:text=Copayment%20Definitions%20for%20the%20Four,some%20brand%20name%20prescription%20drugs> 6. Blue Cross Blue Shield Blue Care Network of Michigan. Updated April 27, 2020. Accessed January 12, 2020. <https://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html>

Specialty Pharmacy



Potential Hurdles in the TSC Journey



What Is a Specialty Pharmacy (SPP)?



A specialty pharmacy is a licensed and accredited pharmacy that provides medications for people with serious health conditions requiring complex therapies such as cancer, hepatitis, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, hemophilia and other bleeding disorders, and rare diseases.¹

Why Do I Need to Use a Specialty Pharmacy?



Health plans and PBMs use a specialty pharmacy to better manage complex chronic conditions often treated with costly medications

The decision to require a medication be dispensed through a specialty pharmacy is impacted by both the manufacturer and the health plan and/or PBM



Hurdles:

- Providers are unaware of SPP requirement
- Individuals don't know which drugs require SPP dispensing
- Individuals don't know which SPP to use or how to find it
- Specialty pharmacies are not like retail, you typically can not just walk into one



Insights:

Locating your SPP network and specialty drugs

- Contact your health plan or PBM using healthcare card
- Online formulary through patient portal
- Manufacturer HUB for prescribed drug can often provide support



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How Does a Specialty Pharmacy Prescription Get Filled?



Typically transmitted electronically (electronic Rx) from doctor's electronic medical record to the pharmacy directly.

SPP reaches out to individual or caregiver through contact information provided on the RX.

First contact usually:

- Establishes disease/condition
- Walks through directions and side effects
- Provides any training needed to give the drug
- Talks about further contact from the SPP as follow-up calls
- Sets up delivery date and reimbursement with individual or caregiver



Hurdles:

- If the prescription is sent to retail pharmacy
- Prescription requires a prior authorization or some form of utilization management
- Financial impact to individual (out of pocket)



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What Happens When My Prescription Is Sent to the Wrong Pharmacy?



Sent to retail pharmacy:

- Retail pharmacy gets notified that Rx must be filled at SPP but doesn't always tell members which SPP is in their network
- With electronic Rx, doesn't really go anywhere from there
- Individual often has to contact the provider's office and tell them where to resend the Rx
- Individual must find out which SPP is in their network and let provider's office know where the Rx must be sent



Insights:

- Ask your retail pharmacy if the payer noted who your specialty pharmacy provider is
- Find out which SPP is allowed to fill your prescription
- Contact your provider office and let them know the Rx must be filled at an SPP and which one they should resend the Rx to
- You may also contact the SPP identified and let them know which retail pharmacy held the original Rx and have them transfer it into the SPP. This can be quicker than involving the provider's office



What Does It Mean When My Prescription Requires a Prior Authorization?



This means there are some things your health insurance company wants to confirm before approving the requested drug, such as:

- Individual's age
 - Diagnosis
 - Previous therapy
 - Prescriber (specialist)
 - Safety concerns
-
- PA can also include requirements to try another product before receiving the requested agent (step therapy) or limit the quantity an individual may receive (quantity limit)
 - If approved, an initial authorization period is assigned to the approval (usually 6-12 months). If denied, an individual may appeal



Insights:

- Some drugs also include reauthorization criteria, which mean conditions that must be met for individuals to continue therapy
- Your SPP will notify your provider that a PA is required and often helps the provider fill out the paperwork
- Make sure your provider has a full history of medications previously tried
- Your SPP will notify you (most often) when your PA has been approved. If it has been denied, TS Alliance has resources that can help with appeals
- Your SPP will call to set up payment and delivery
- If it has been more than 72 hours, contact your SPP and your provider's office for the status of the PA request



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What If I Cannot Afford My Prescription?



How much you owe for your prescription depends on many things:

- Type of health plan (high deductible)
- Deductible
- Formulary tier
- Cost of your medication



Insights:

- SPP can help you locate financial assistance
- HUB by pharmaceutical company for prescribed drug can help

Types of financial assistance:

- Copay/discount card (commercial members)
- Patient assistance program (income based)
 - SPP/HUB can assist with completion of paperwork
- Foundation's Medicare members may need to ask SPP if there are any programs available for the prescribed drug



Your Team and the Transition to Adulthood

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The Tuberous Sclerosis Alliance (TS Alliance) was founded in 1974 and is an internationally recognized nonprofit organization dedicated to finding a cure for tuberous sclerosis complex (TSC) while improving the lives of those affected¹



Goals

**Accelerate
Research**

**Improve Access
and Quality
of Care**

**Support and
Empower
Constituents**

**Educate and
Mobilize to
Increase
Investment**

**Build and
Strengthen
Organization**

Current TS Alliance Partnerships



The Alliance for Genetic Etiologies in Neurodevelopmental Disorders and Autism (AGENDA): <https://www.allianceagenda.org/>

American Thoracic Society Public Advisory Roundtable (ATS PAR): <https://www.thoracic.org/patients/par/>

The Arc: <https://thearc.org/>

Child Neurology Foundation: <https://www.childneurologyfoundation.org/>

Epilepsy Leadership Council: <https://www.epilepsyleadershipcouncil.org/>

Global Genes: <https://globalgenes.org/>

Infantile Spasms Action Network: <https://infantilespasms.org/>

The National Organization for Rare Disorders (NORD): <https://rarediseases.org>

Rare Epilepsy Network: <https://www.rareepilepsynetwork.org/>

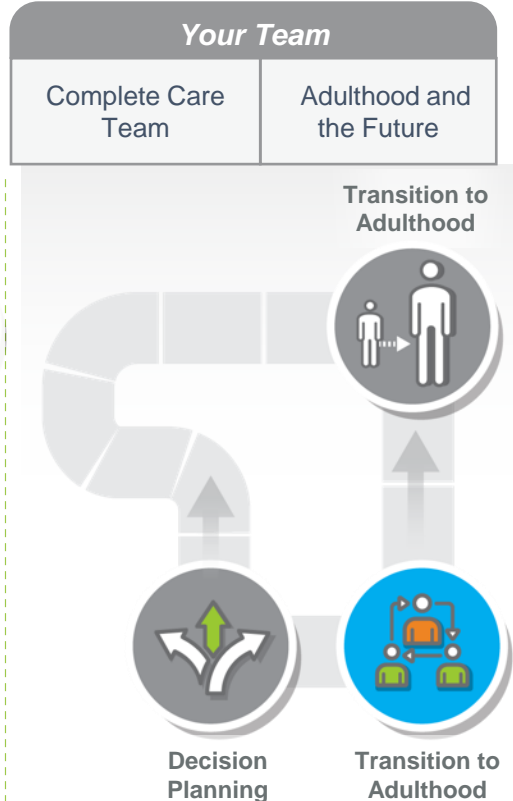
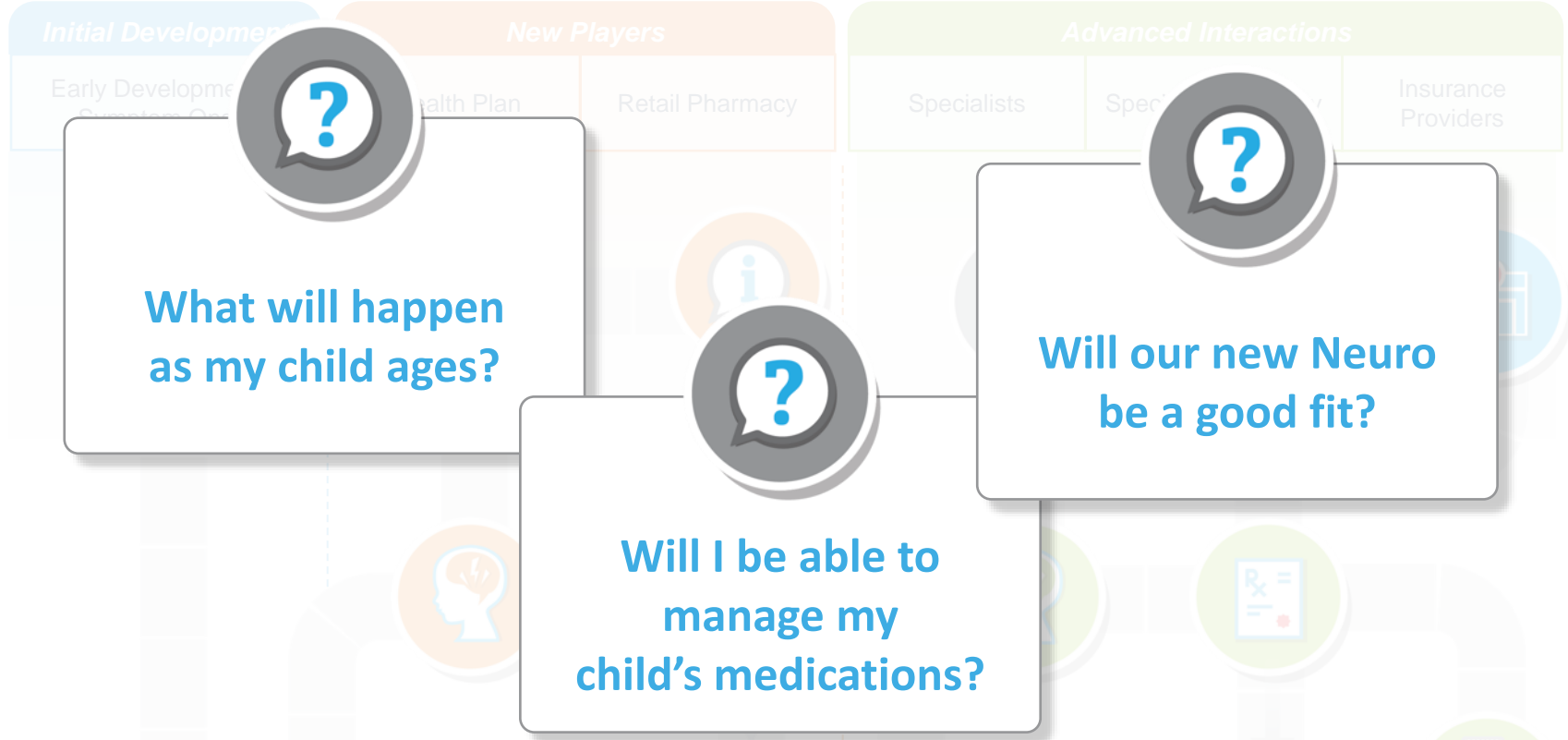
Seizure Action Plan (SAP) Coalition: <https://www.seizureactionplans.org/>



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Potential Hurdles in the TSC Journey



Insights:

- File appropriate paperwork with pharmacy, health plan, and PBM to be able to manage child's medication as they approach teenage years
- Work with a pediatric neurologist to align on an adult provider and begin forming the relationship as child approaches their teenage years





Digital Resources:

- **Perspective magazine:** published twice yearly
- **TSC Matters:** bimonthly e-newsletter
- **TSC Alert:** monthly e-newsletter for researchers and healthcare professionals
- **TSC Now:** monthly podcast series
- **TSC TV:** webinars and videos



2021 Webinar Series – 28 different educational topics, including:

- Life Stages of TSC
- TSC-Associated Neuropsychiatric Disorders (TAND)
- Transitions Workshops
- Research and Clinical Trial Updates

[Landing Page](#)





TSC Navigator

- The **TSC Navigator** is an online portal to help guide you and your healthcare team along your TSC journey. The TS Alliance acknowledges that each person's journey is unique, therefore, bridging the gap within the existing healthcare system and decreasing the barriers to care and access to FDA-approved treatment is a priority
- The **TSC Navigator** is essential in providing accurate, up-to-date, high-quality care support, treatment coordination, and advocacy for each need for all individuals with TSC and their families across the lifespan of TSC
- No matter where you are in your journey, the TSC Navigator is there to find the support and guidance you deserve

“Do what you can, with what you’ve got, where you are.”¹

– Theodore Roosevelt

Your TS Alliance Support Navigators



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Summary and Q&A

Key Takeaways



- ✔ Health plans and PBMs make coverage decisions through committees comprised of practicing physicians, pharmacists, and nurses
- ✔ Specialty pharmacies are used to maximize clinical outcomes in complex chronic conditions
- ✔ Be PROACTIVE in understanding your pharmacy benefits and communicating with providers
- ✔ Know which drugs require SPP dispensing and what your specialty pharmacy is
- ✔ Individuals should track when authorizations will expire and keep enough drug on hand
- ✔ SPPs can help with affordability through various program. Ask about available programs
- ✔ As adulthood approaches, supply appropriate documents in preteen years to reduce disruption
- ✔ The TS Alliance has numerous resources available for members. Contact TS Alliance Support Navigators with any questions or concerns

