### National and Medicaid Specialty Drug Trends

#### National Specialty Drug Trend (2014)
- Increase from 25% to 30% of total pharmacy spend
- Autoimmune disorders top ranked class by cost
- Hepatitis C is fourth-ranked class by cost

#### Medicaid Specialty Drug Trend (2014)
- 35.8% increase in specialty drug spend
- Represents ~ 28% of total pharmacy drug spend
- Top three drug classes
  - *Hepatitis C, HIV, Inflammatory conditions*
- Increase primarily driven by three new hepatitis C drugs
  - *Harvoni®, Olysio®, Sovaldi®*
National Medicaid Specialty Drug Trends

Top 5 Medicaid Specialty Drug Classes (2014) by PMPY Spend

- Hepatitis C
- HIV/AIDS
- Inflammatory Conditions
- Oncology
- Multiple Sclerosis
Hepatitis C Drugs

• Largest impact on Medicaid programs in 2014
• 1 in 5 Hepatitis C patients covered in state-funded healthcare programs
  – Medicaid
  – Prison systems
• Therapy course can cost up to $189,000 per patient
## Projected Budgetary Impact of Specialty Drugs

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<tbody>
<tr>
<td>Overall Specialty Drug Spend</td>
<td>15%</td>
<td>39%</td>
<td>18%–24%</td>
<td>18%–24%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Data not available</td>
<td>180%</td>
<td>50%–75%</td>
<td>40%–65%</td>
</tr>
<tr>
<td>Pulmonary (Cystic Fibrosis)</td>
<td>Data not available</td>
<td>12%–17%</td>
<td>70%–75%</td>
<td>150%–200%</td>
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### North Carolina Medicaid Specialty Drug Trends

#### Annual Specialty Drug Utilization
- SFY 2012: 15.5% of Pharmacy Spend
- SFY 2013: 17.4% of Pharmacy Spend
- SFY 2014: 21.8% of Pharmacy Spend

#### Monthly Specialty Drug Utilization
- SFY 2014 Range: 18.2%-27.0%
### Reimbursement Strategies

- Increase discounts off of Wholesale Acquisition Cost
- 340B and non-340B reimbursement rates
- Lowers drug ingredient costs prior to payment

### Standards of Care

- Ensure patients receive optimal care across providers
- Ensure patients receive consistent care across providers
- Prevents overutilization and waste
### North Carolina Medicaid
Current Specialty Drug Management Strategies

<table>
<thead>
<tr>
<th>Preferred Drug List</th>
<th>Prior Authorization</th>
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<tbody>
<tr>
<td>• Increases supplemental rebates received from pharmaceutical manufacturers</td>
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<tr>
<td>• Lowers net drug costs after payment</td>
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<tr>
<td>• Ensures use according to FDA indications and guidelines for use</td>
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<tr>
<td>• Prevents overutilization and waste</td>
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</tbody>
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North Carolina Medicaid Enhanced Specialty Drug Discount List

• NC Session Law 2008-107, Section 10.10(e)
  – Mandate to use state upper limit cost basis methodology for specialty drugs
  – Single source specialty drugs in excess of $1,500 cost per month

• Current cost basis methodology is Wholesale Acquisition Cost + 1%

• Currently more than 300 unique specialty drugs on our list
North Carolina Medicaid Hemophilia Specialty Pharmacy Program

- NC Session Law 2012-142, Section 10.48(a2)
  - *Mandate to establish hemophilia specialty drug program*
  - *340B and Non-340B Reimbursement Strategy*
- Standards of Care Across Providers
- Provider Reporting Requirements to Ensure Treatment Outcomes
PDL Rebates Lower Net Drug Costs

- Hepatitis C
- Rheumatoid Arthritis and Other Inflammatory Conditions
- Growth Hormones
- Multiple Sclerosis
North Carolina Medicaid
Prior Authorization Programs – Hepatitis C Drugs

Hepatitis C Drugs Prior Authorization

• Criteria follow FDA guidelines for age and diagnosis
• Criteria follow FDA dosing and therapy duration guidelines
• Medical documentation required for diagnosis of chronic hepatitis C
• Patient commitment to abstinence with history of alcohol and IV drug use
• Patient must meet all beneficiary readiness criteria
Synagis® Prior Authorization

- Criteria follow the American Academy of Pediatrics (AAP) Committee on Infectious Diseases guidelines
- Updated for the 2014-2015 RSV season which narrowed the criteria for evidence-based use
- Prior authorization is made through the Document for Safety website which allows specialist evaluation of medical necessity as well as weight-appropriate dosing
- Document for Safety is a joint initiative between DMA and CCNC
Specialty Drug Management Strategies
Future Considerations

Standards of Care/Reimbursement Strategies
- Hepatitis C, Cystic Fibrosis, HIV/AIDS, RA, and Other Inflammatory Conditions

Clinical and Utilization Management
- New prior authorization programs
- New step therapy programs

Site of Service Management
- Pharmacy versus medical program coverage
- Requires reimbursement rate updates under the Physicians Drug Program
Specialty drugs continue as key drivers over the next two years

- Inflammatory Conditions: ~11 new drugs
- Cancer: ~70+ new drugs with more oral formulations
- Hepatitis C: ~12 new drugs
- Hypercholesterolemia: PCSK9 Inhibitors
  - Early estimates of annual costs per patient: $6,000 - $10,000
  - Early estimate on treatment adoption rate of 30%-50%
References