CENTENE PHARMACY AND THERAPEUTICS
DRUG REVIEW
3Q17 July-August

BRAND NAME
Sovaldi®

GENERIC NAME
sofosbuvir

MANUFACTURER
Gilead Sciences, Inc.

DATE OF APPROVAL
April 7, 2017

PRODUCT LAUNCH DATE
Product is already on the market

REVIEW TYPE

☐ Review type 1 (RT1): New Drug Review
Full review of new chemical or biologic agents

☒ Review type 2 (RT2): New Indication Review
Abbreviated review of new dosage forms of existing agents that are approved for a new indication or use

☐ Review type 3 (RT3): Expedited CMS Protected Class Drug Review
Expedited abbreviated review of Centers for Medicare & Medicaid Services protected class drugs (anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants)

☐ Review type 5 (RT5): Abbreviated Review for Intravenous Chemotherapy Agents
Abbreviated review for intravenous chemotherapy agents which are usually covered under the medical benefit

FDA APPROVED INDICATION(S)

Current Indication(s)
For the treatment of chronic hepatitis C virus (HCV) in adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.

CENTENE PHARMACY AND THERAPEUTICS
DRUG REVIEW
3Q17 July-August

New/Revised Indication(s)
For the treatment of chronic hepatitis C virus (HCV) in pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin

OFF-LABEL USES
Not applicable

CLINICAL EFFICACY
The safety and efficacy of Sovaldi in pediatric patients was investigated in an open-label phase 2 clinical study. Fifty patients age 12 to 17 years of age or weighing at least 35 kg with or without cirrhosis were included in the study. Subjects with HCV genotype 2 (N=13) and subjects with HCV genotype 3 (N=37) received 400 mg of Solvadi plus weight based ribavirin. The duration of treatment for genotype 2 was12 weeks and 24 weeks for genotype 3. The sustained virologic response (SVR) 12 rate was 100% (13/13) in genotype 2 patients and 97% (36/37) in genotype 3 patients. No subject experienced on-treatment virologic failure or relapse.

CONTRAINDICATIONS
None identified

BLACK BOX WARNINGS
None identified

DRUG INTERACTIONS
- Coadministration with amiodarone may result in serious symptomatic bradycardia.
- Use of Sovaldi with amiodarone is not recommended.
- P-gp inducers (e.g., rifampin, St. John's wort): May alter concentrations of Sovaldi. Use of Sovaldi with P-gp inducers is not recommended.

ADVERSE REACTIONS
The most common adverse events (incidence greater than or equal to 15%, all grades) observed with Sovaldi in combination with ribavirin were fatigue, headache, and nausea. Theses commonly reported adverse reactions were comparable to that observed in adults.

DOSAGE AND ADMINISTRATION
The recommended dosage of Sovaldi in pediatric patients 12 years of age and older or weighing at least 35 kg is one 400 mg tablet taken orally once daily with or without food in combination with ribavirin for 12 weeks for patients with Genotype 2 and 24 weeks for patients with Genotype 3.

PRODUCT AVAILABILITY

CENTENE PHARMACY AND THERAPEUTICS
DRUG REVIEW
3Q17 July-August

Tablet: 400 mg sofosbuvir

THERAPEUTIC ALTERNATIVES
This section is intentionally left blank

Utilization Management Recommendation
• There is significant potential for inappropriate use and utilization management should be considered for the following reason(s): i) To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes. (1) Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of the medication. (a) FDA indication is specific to genotype, treatment history, and cirrhosis status to identify candidates for treatment for specific duration of therapy. ii) Recommended utilization management tool(s): (check all that apply) (1) ☒ Prior authorization (2) ☐ Quantity limits (3) ☐ Provider newsletter (4) ☐ Hard block (plan exclusion) (5) ☐ Messaging (6) ☐ Electronic step therapy (7) ☐ Clinical Program
Product Comparison
• This section is intentionally left blank

REFERENCES:

1. Sovaldi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; April 2017. Available at http://www.sovaldi.com/. Accessed April 10, 2017.
2. HCV guidance: Recommendations for testing, managing, and treating hepatitis C. AASLD-IDSA. Available at http://www.hcvguidelines.org. Accessed April 10, 2017.
3. Wirth et al. Sofosbuvir-Containing Regimens are Safe and Effective in Adolescents with Chronic hepatitis C Infection. 26th Annual Meeting of the Asian pacific Association for the Study of the Liver (APASL) on February 15-19, 2017 in Shangahi, China [oral GT1-3].
4. El-Shabrawi MH, Kamal NM. Burden of pediatric hepatitis C. World J Gastroenterol. 2013 Nov 28;19(44):7880-8. doi: 10.3748/wjg.v19.i44.7880.

5. Wirth S. Current treatment options and response rates in children with chronic hepatitis C. World J Gastroenterol 2012 Jan 14; 18(2): 99-104. doi:10.3748/wjg.v18.i2.99.