



Medication Policy Manual

Policy No: dru332

Topic: Sovaldi™, sofosbuvir

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IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Sofosbuvir (Sovaldi) is an oral antiviral medication that is given in combination with ribavirin or in combination with peginterferon alfa (PEG-Intron®, Pegasys®) and ribavirin for the treatment of chronic genotype 1, 2, 3, or 4 hepatitis C virus (HCV) infection.

Policy/Criteria

- I.** Most contracts require prior authorization approval of sofosbuvir prior to coverage. Sofosbuvir may be considered medically necessary when criterion A, B, C, or D below is met.

CHRONIC HEPATITIS C GENOTYPE 1

- A.** There is a diagnosis of chronic genotype 1 hepatitis C virus (HCV) infection and criteria 1 through 6 below are met:

- 1.** Ribavirin will be used in combination with sofosbuvir.

AND

- 2.** Peginterferon will be used in combination with sofosbuvir and ribavirin, unless peginterferon is contraindicated or is not a treatment option (see *Appendix 2*).

AND

- 3.** The member has not been previously treated with any of the following medications: boceprevir (Victrelis), simeprevir (Olysio), sofosbuvir (Sovaldi), or telaprevir (Incivek).

AND

- 4.** The member has advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4), as documented by criterion a or b below:

- a.** Liver biopsy.

OR

- b.** Non-invasive markers of liver fibrosis (for example an ultrasound, CT scan, liver elastography, FibroScan, FIB-4 score, or other serum fibrosis marker panels).

AND

- 5.** There is documentation that the member has had no marijuana use, alcohol abuse, or intravenous (IV) drug use in the previous six months.

AND

- 6.** Sofosbuvir is dispensed from a pharmacy that has demonstrated the ability to provide the clinical support services outlined in *Appendix 3*.

CHRONIC HEPATITIS C GENOTYPE 2 OR 3

- B.** There is a diagnosis of chronic genotype 2 or genotype 3 hepatitis C virus (HCV) infection and criteria 1 through 5 below are met:

- 1.** Ribavirin will be used in combination with sofosbuvir.

AND

- 2.** The member has not been previously treated with sofosbuvir (Sovaldi).

AND

- 3.** The member has advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4), as documented by criterion a or b below:

- a. Liver biopsy.

OR

- b. Non-invasive markers of liver fibrosis (for example an ultrasound, CT scan, liver elastography, FibroScan, FIB-4 score, or other serum fibrosis marker panels).

AND

- 4. There is documentation that the member has had no marijuana use, alcohol abuse, or intravenous (IV) drug use in the previous six months.

AND

- 5. Sofosbuvir is dispensed from a pharmacy that has demonstrated the ability to provide the clinical support services outlined in *Appendix 3*.

CHRONIC HEPATITIS C GENOTYPE 4

- C. There is a diagnosis of chronic genotype 4 hepatitis C virus (HCV) infection and criteria 1 through 5 below are met:

- 1. Peginterferon and ribavirin will be used in combination with sofosbuvir.

AND

- 2. The member has not been previously treated with any of the following medications: boceprevir (Victrelis), simeprevir (Olysio), sofosbuvir (Sovaldi), or telaprevir (Incivek).

AND

- 3. The member has advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4), as documented by criterion a or b below:

- a. Liver biopsy.

OR

- b. Non-invasive markers of liver fibrosis (for example an ultrasound, CT scan, liver elastography, FibroScan, FIB-4 score, or other serum fibrosis marker panels).

AND

- 4. There is documentation that the member has had no marijuana use, alcohol abuse, or intravenous (IV) drug use in the previous six months.

AND

- 5. Sofosbuvir is dispensed from a pharmacy that has demonstrated the ability to provide the clinical support services outlined in *Appendix 3*.

HEPATOCELLULAR CARCINOMA / PRE-LIVER TRANSPLANT

- D. There is a diagnosis of chronic hepatitis C virus (HCV) infection and criteria 1 through 4 below are met:

- 1. There is a diagnosis of hepatocellular carcinoma (HCC).

AND

2. The member is awaiting liver transplantation.
- AND
3. Sofosbuvir will be given in combination with ribavirin.
- AND
4. Sofosbuvir is dispensed from a pharmacy that has demonstrated the ability to provide the clinical support services outlined in *Appendix 3*.

II. Administration, Quantity Limitations, and Authorization Period

- A. RegenceRx considers sofosbuvir to be a self-administered medication.
- B. When prior authorization is approved, sofosbuvir may be authorized as follows:

1. **Genotype 1:**
 - a. **In combination with peginterferon and ribavirin:** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of 12 weeks (one treatment course).
 - b. **In combination with ribavirin only (peginterferon is contraindicated or is not a treatment option; see *Appendix 2*):** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of 24 weeks (one treatment course).
2. **Genotype 2 (in combination with ribavirin):** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of 12 weeks (one treatment course).
3. **Genotype 3 (in combination with ribavirin):** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of 24 weeks (one treatment course).
4. **Genotype 4 (in combination with peginterferon and ribavirin):** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of 12 weeks (one treatment course).
5. **Hepatocellular carcinoma / pre-liver transplant:** up to #28 sofosbuvir 400 mg tablets per 28 days for a total duration of up to 48 weeks (one treatment course).

III. Sofosbuvir is considered not medically necessary when used in combination with boceprevir, simeprevir, or telaprevir.

IV. Sofosbuvir is considered investigational when used:

- A. As monotherapy.
- B. As retreatment when there has been relapse after, or no response to, a prior treatment course with boceprevir, simeprevir, sofosbuvir, or telaprevir.
- C. For the treatment of recurrent HCV infection following liver transplantation.

Position Statement

- Sofosbuvir is an oral hepatitis C virus (HCV) polymerase inhibitor that is used in combination with ribavirin or in combination with peginterferon and ribavirin for the treatment of chronic genotype 1, 2, 3, or 4 HCV infection, including patients co-infected with human immunodeficiency virus (HIV).
- Sofosbuvir has been shown to be safe and effective for treating chronic HCV infection in treatment-naïve patients, as well as patients with certain genotypes who relapsed after or did not respond to prior treatment with peginterferon and ribavirin. There is currently no published data supporting the efficacy of sofosbuvir in patients who have failed prior therapy with a direct-acting oral antiviral for HCV infection (e.g. boceprevir, simeprevir, sofosbuvir, or telaprevir).
- Sofosbuvir is also approved for use in combination with ribavirin for patients with chronic HCV infection who have hepatocellular carcinoma (HCC) and are awaiting liver transplantation.
- The duration of treatment with sofosbuvir is determined by HCV genotype, concomitant HCV therapy, and if it is being used in the pre-liver transplant setting.
- The dose of sofosbuvir is 400 mg by mouth once daily for a total of 12 weeks in patients with chronic genotype 2 or 4 HCV infection, and most patients with chronic genotype 1 HCV infection. It is dosed for 24 weeks in genotype 3 patients, as well as in genotype 1 patients who are ineligible for peginterferon therapy (see *Appendix 2*). When used for chronic HCV infection in patients with HCC who are awaiting a liver transplant, sofosbuvir may be dose for up to 48 weeks or until liver transplantation, whichever occurs first.
- The safety and efficacy of sofosbuvir monotherapy have not been established.
- The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) clinical practice guidelines state that patients with the highest priority for treatment owing to highest risk for severe complications are those with advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4), based on high quality evidence.^[2]
- Sofosbuvir is currently being studied in a variety of HCV clinical settings, including in post-liver transplant patients with recurrent HCV infection; however, there is currently no published data to support the efficacy and safety of sofosbuvir in these settings.

Clinical Efficacy

Genotypes 1, 4, 5, and 6

The addition of sofosbuvir to peginterferon and ribavirin has been shown to produce high viral cure rates in patients with chronic genotype 1, 4, 5, or 6 hepatitis C virus (HCV) infection; however, the supporting evidence is not of high certainty.

- One low confidence, single-arm published trial (NEUTRINO) evaluated the addition of sofosbuvir to peginterferon and ribavirin for a 12 week treatment course in treatment-naïve HCV genotype 1, 4, 5, and 6 patients. ^[3]
- The majority of patients included in the trial were HCV genotype 1 (89%), followed by HCV genotype 4 (9%). Only one patient with HCV genotype 5 and six patients with genotype 6 were included in the trial. ^[3]
- The primary endpoint evaluated was the rate of viral cure, defined as a sustained virologic response (SVR) 12 weeks following the completion of therapy. Although SVR is measured by a series of HCV RNA levels and is considered a surrogate endpoint, it is accepted as a measure of efficacy for the treatment of HCV. ^[3]
 - * The reported SVR rate was 90% with sofosbuvir, peginterferon, and ribavirin. This SVR rate was reported to be a statistically significant improvement when compared to the historical SVR rate of 60% with peginterferon and ribavirin ($P < 0.001$), however, it is unknown if the study population and historical population were sufficiently similar for comparison. ^[3]
 - * The reported SVR rates were 89%, 96%, 100%, and 100% for genotypes 1, 4, 5, and 6, respectively. ^[3]
 - * According to the FDA medical review, too few patients with genotypes 5 and 6 were included in the trial to establish efficacy, safety, and appropriate dosing for those genotypes. ^[4] Sofosbuvir did not receive FDA-approval for the treatment of HCV genotypes 5 and 6.
- The magnitude of benefit with sofosbuvir cannot be accurately estimated due to lack of a true control group.
- There are no published trials evaluating the safety and efficacy of sofosbuvir in treatment-experienced patients with HCV genotypes 1, 4, 5, or 6, or comparing sofosbuvir to other treatment options for HCV genotypes 1, 4, 5, and 6.
- Clinical practice guidelines from AASLD and IDSA recommend the combination of sofosbuvir, peginterferon, and ribavirin for treatment-naïve patients with chronic genotype 1, 4, 5, or 6 HCV infection, including those co-infected with HIV, and for treatment-experienced patients with chronic genotype 4, 5, or 6 HCV infection. ^[2]
- This guideline also recommends the combination of sofosbuvir, peginterferon, and ribavirin for patients with partial or null response to prior therapy that included boceprevir or telaprevir; however, it is unclear what clinical efficacy data this recommendation is based on. ^[2]

Genotype 2 and 3

The combination of sofosbuvir and ribavirin has been shown to improve viral cure rates relative to placebo, and produce a similar viral cure rate as peginterferon and ribavirin, in patients with HCV genotype 2 or 3; however, the supporting evidence is not of high certainty.

- One fair confidence, published, open-label randomized controlled trial (POSITRON) and one low confidence, published, open-label randomized controlled trial (VALENCE)

evaluated the combination of sofosbuvir and ribavirin vs placebo in patients with chronic genotype 2 or 3 HCV infection. ^[1,4,5,7]

- * The POSITRON trial only included patients with past intolerance or a medical contraindication to interferon-based therapy. The VALENCE trial included both treatment-naïve and treatment-experienced patients.
- * The primary endpoint evaluated in these trials was the rate of viral cure, defined as a sustained virologic response (SVR) 12 weeks following the completion of therapy. Although SVR is measured by a series of HCV RNA levels and is considered a surrogate endpoint, it is accepted as a measure of efficacy for the treatment of HCV.
- * The reported SVR rates for sofosbuvir and ribavirin treatment were 78-93% vs 0% with placebo.
- * The POSITRON trial demonstrated higher SVR rates in genotype 2 patients than in genotype 3 patients who were treated for 12 weeks (93% vs 61%, respectively). Therefore, another low confidence trial (FUSION) and the VALENCE trial evaluated longer durations of sofosbuvir and ribavirin treatment in HCV genotype 3 patients (16 and 24 weeks, respectively). ^[1, 4,5]
- * The FUSION and VALENCE trials demonstrated that 16 or 24 weeks of treatment in genotype 3 patients resulted in improved SVR rates (62% and 84%, respectively). ^[1,4,5,7]
- One fair confidence, published, randomized, open-label, non-inferiority study (FISSION) evaluated the efficacy of sofosbuvir and ribavirin relative to peginterferon and ribavirin in treatment-naïve HCV genotype 2 or 3 patients. ^[3]
 - * The primary endpoint evaluated in these trials was the rate of viral cure, defined as a sustained virologic response (SVR) 12 weeks following the completion of therapy. Although SVR is measured by a series of HCV RNA levels and is considered a surrogate endpoint, it is accepted as a measure of efficacy for the treatment of HCV.
 - * The reported SVR rate in both treatment groups was 67%, which demonstrated non-inferiority of sofosbuvir and ribavirin relative to peginterferon and ribavirin.
- Clinical practice guidelines from AASLD and IDSA recommend the combination of sofosbuvir and ribavirin in treatment-naïve or treatment-experienced patients with chronic genotype 2 or 3 HCV infection. ^[2]

Hepatocellular Carcinoma in Patients Awaiting Liver Transplantation

There are no published randomized controlled trials evaluating the combination of sofosbuvir and ribavirin in patients with chronic HCV infection and hepatocellular carcinoma who are awaiting liver transplantation.

- One unpublished trial evaluated the combination of sofosbuvir and ribavirin in HCV-infected patients with hepatocellular carcinoma who were awaiting liver transplantation

- (n = 61). Patients were treated for up to 48 weeks or until transplantation, whichever occurred first. ^[1,4]
- Post-transplant virologic response (pTVR) was evaluated as the primary endpoint. pTVR is defined as serum HCV RNA below the lower limit of quantification (undetectable) at 12 weeks post-transplant. Although this is a surrogate endpoint, it is a similar endpoint to SVR and a well-accepted measure of HCV treatment success. ^[1,4]
 - Forty-one patients underwent liver transplant, and of those 56% achieved pTVR.
 - The magnitude of benefit with sofosbuvir and ribavirin in this setting cannot be accurately estimated due to lack of a control group and small sample size. ^[1,4]
 - Clinical practice guidelines from AASLD and IDSA recommend the combination of sofosbuvir and ribavirin for patients with any HCV genotype who have hepatocellular carcinoma who may or may not be candidates for liver transplantation. ^[2]

HCV/HIV Co-Infection

There are no published randomized controlled trials evaluating the combination of sofosbuvir and ribavirin in patients with chronic HCV infection who are co-infected with HIV.

- One unpublished trial (PHOTON-1) evaluated the combination of sofosbuvir and ribavirin in patients with chronic genotype 1, 2, or 3 HCV infection who were co-infected with HIV (n = 223). Patients with genotype 1 HCV infection were treatment-naïve, whereas genotype 2 or 3 patients were treatment-naïve or treatment-experienced. ^[1,4]
- The primary endpoint evaluated was the rate of viral cure, defined as a sustained virologic response (SVR) 12 weeks following the completion of therapy. Although SVR is measured by a series of HCV RNA levels and is considered a surrogate endpoint, it is accepted as a measure of efficacy for the treatment of HCV. ^[1,4]
- The reported SVR rates for genotypes 1, 2, and 3 were 76%, 88%, and 92%, respectively. ^[1,4]
- The magnitude of benefit cannot be accurately estimated due to lack of a comparator group and low numbers of genotype 2 and 3 patients included in the trial.
- Data from this trial were used to support the FDA-approved indication for the use of sofosbuvir and ribavirin without peginterferon for 24 weeks in chronic genotype 1 HCV patients who are interferon ineligible. ^[4]
- Clinical practice guidelines from AASLD and IDSA recommend that patients co-infected with HCV and HIV receive the same therapy as those mono-infected with HCV (see recommendations above). ^[2]

Other Uses

- Sofosbuvir is currently being studied in a variety of HCV clinical settings, including in post-liver transplant patients with recurrent HCV infection; however, there is currently no published data to support the efficacy and safety of sofosbuvir in these settings.
- A low confidence open-label phase II study (COSMOS) evaluated the efficacy and safety of sofosbuvir in combination with simeprevir with or without ribavirin for patients with HCV genotype 1 who were treatment-naïve or were prior null responders. ^[6]
 - * COSMOS consisted of two cohorts. Cohort 1 (n = 80) included patients who were prior null responders to peginterferon and ribavirin with no liver fibrosis or mild-to-

moderate liver fibrosis (Metavir F0-F2 scores). Cohort 2 (n = 87) included treatment-naïve patients and prior null responders to peginterferon and ribavirin with significant liver fibrosis, including cirrhosis (Metavir F3-F4 scores).

- * The primary endpoint was the rate of viral cure, defined as a sustained virologic response 12 weeks following the completion of therapy (SVR12). Although SVR is measured by a series of HCV RNA levels and is considered a surrogate endpoint, it is accepted as a measure of efficacy for the treatment of HCV.
- * In cohort 1, SVR12 ranged from 79%-96% depending on treatment group, with the highest SVR rates in patients treated with sofosbuvir, simeprevir, and ribavirin for 12 weeks. In cohort 2, SVR12 ranged from 93%-100%, with the highest SVR rates in patients treated with sofosbuvir and simeprevir for 24 weeks.
- * Concerns with the quality of this trial include the small numbers of patients included in each treatment group (≤ 30) and lack of a control group.
- * Clinical practice guidelines from AASLD and IDSA recommend the combination of sofosbuvir and simeprevir in patients with chronic genotype 1 HCV infection who are treatment-naïve and interferon ineligible (see *Appendix 2*), and in patients with chronic genotype 1 HCV infection who were partial or null responders to prior treatment with peginterferon and ribavirin. ^[2]
- * The combination of sofosbuvir and simeprevir has not been shown to be superior to other regimens for HCV genotype 1, including other sofosbuvir- or simeprevir-containing regimens.

Safety ^[1]

- The most common adverse events with sofosbuvir, peginterferon, and ribavirin were fatigue, nausea, and anemia. The absolute increase of these side effects vs peginterferon and ribavirin alone was 4%, 5%, and 9%, respectively (cross-trial comparison).
- The most common adverse events with sofosbuvir and ribavirin were headache and fatigue, which occurred at an absolute increased frequency of 4-6% and 6-14%, respectively, vs placebo.
- Sofosbuvir (Sovaldi) is not associated with CYP 3A drug-drug interactions. It is a substrate of P-gp, so strong P-gp inducers (e.g. rifampin or St. John's Wort) may decrease the plasma concentration of sofosbuvir.

Liver Fibrosis Status ^[2]

- The American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) treatment guidelines recommend an evaluation for advanced liver fibrosis using liver biopsy, imaging, or non-invasive markers for all patients with HCV infection in order to determine the treatment strategy.
 - * Liver biopsy can provide objective information about the level of liver fibrosis and inflammation, which assists with treatment and monitoring plans. Liver biopsy can be used in conjunction with Metavir or Ishak fibrosis scores to determine the

severity of liver fibrosis present. Liver biopsy carries some risk of complication, although this risk is low.

- * Non-invasive methods used to estimate liver disease severity include routine blood tests (e.g. serum alanine transaminase, albumin, bilirubin, INR, complete blood counts, and platelets), serum fibrosis marker panels, liver imaging (e.g. ultrasound, CT scan) and liver elastography. These methods may help determine the likelihood of developing future liver complications or distinguish cirrhosis from non-cirrhosis, but may not be sufficient to determine the severity of liver fibrosis.

Dosing Considerations

- The dose of sofosbuvir is 400 mg (one tablet) by mouth once daily with or without food. ^[1]
- The duration of therapy with sofosbuvir is dependent on genotype: ^[1]
 - * Genotype 1: in combination with peginterferon and ribavirin for 12 weeks. Interferon ineligible patients may be treated with sofosbuvir and ribavirin for 24 weeks.
 - * Genotype 2: in combination with ribavirin for 12 weeks.
 - * Genotype 3: in combination with ribavirin for 24 weeks.
 - * Genotype 4: in combination with peginterferon and ribavirin for 12 weeks.
 - * Genotypes 5 and 6: not indicated.
- HCV patients who have hepatocellular carcinoma and are awaiting liver transplant are treated for up to 48 weeks or until liver transplantation, whichever occurs first. ^[1]
- The recommended duration of treatment with sofosbuvir and simeprevir is 12 weeks. ^[2]

Pharmacy Support Services

- The treatment of HCV infection is unique and complex. The increased level of care provided by clinical pharmacists may improve the chances of treatment success:
 - * Treatment with sofosbuvir is a one-time treatment that is limited to 12 to 24 weeks (or up to 48 weeks for patients with hepatocellular carcinoma awaiting liver transplantation).
 - * Treatment is more likely to be successful if it is continued without interruption.

Appendix 1: Definitions of Member Treatment History

Treatment-naive	Patients who have never received therapy for the treatment of hepatitis C.
Relapser	Patients who had an undetectable HCV RNA level at the end of prior therapy with peginterferon and ribavirin, but had a subsequent detectable HCV RNA level during the follow-up period.
Partial responder	Patients who had a HCV RNA reduction of $\geq 2 \log_{10}$ after 12 weeks of prior therapy with peginterferon and ribavirin, but still had a detectable HCV RNA level during the treatment period.
Null responder	Patients who had a $< 2 \log_{10}$ reduction in HCV RNA after 12 weeks of prior therapy with peginterferon and ribavirin.

Appendix 2: Absolute and Relative Contraindications to Peginterferon Therapy ^[2]

- Intolerance to (peg)interferon
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to (peg)interferon or any of its components
- Decompensated hepatic disease
- History of depression, or clinical features consistent with depression
- A baseline neutrophil count $< 1,500/\mu\text{L}$, a baseline platelet count $< 90,000/\mu\text{L}$, or baseline hemoglobin $< 10 \text{ g/dL}$
- A history of preexisting cardiac disease

Appendix 3: Clinical pharmacy support services necessary for dispensing sofosbuvir (Sovaldi) to RegenceRx members

- 1) Implement a comprehensive patient intake assessment to identify potential drug-drug interactions, confirm the appropriate duration of therapy, and identify any unique patient-specific needs or barriers to completing treatment for chronic hepatitis C.
- 2) Issue refill reminders to assist members in adhering to his or her treatment regimen for the entire medically-necessary duration of therapy.
- 3) Provide the minimum necessary quantities in alignment with RegenceRx coverage policies to reduce the potential for waste, while ensuring therapy is not unnecessarily interrupted.
- 4) Demonstrate the ability to dispense partial month fills.
- 5) Demonstrate redundancy in systems for both the storage and shipping of medications. Medications must be supplied within 48 hours of receiving a prescription order.
- 6) Provide assistance to members in scheduling laboratory blood draws to measure viral response that can guide therapy and determine the need for continuing treatment.
- 7) Monitor adverse effects through the use of regularly scheduled follow-up telephone consultations and the use of a systematic screening tool to identify and assist patients in the management of adverse effects.
- 8) Provide a dedicated team of clinical pharmacists for RegenceRx membership.
- 9) Provide 24 hours per day, 7 days per week availability of clinical support staff for members.
- 10) Provide documentation of current ACHC and URAC accreditation.
- 11) Provide reports to RegenceRx at least quarterly that describe the following:
 - Number of patients enrolled in the hepatitis C management program
 - Adherence data for each patient enrolled, including dispensing dates, number of days supply dispensed, and reason for treatment discontinuation, if patient discontinued treatment early
 - Documentation of dates when patients were contacted
 - Documentation of the first hepatitis C RNA level after the start of protease inhibitor therapy

Note: RegenceRx reserves the right to establish whether the above conditions have been met and may revoke pharmacy approval status at any time.

Cross References

Incivek[®], telaprevir, dru254

Pegasys[®], peginterferon alfa-2a, dru044

PEG-Intron[®], peginterferon alfa-2b, dru144

Sovaldi[™], sofosbuvir, dru332

Victrelis[®], boceprevir, dru253

Codes	Number	Description
N/A		

References

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