



CALIFORNIA TECHNOLOGY
ASSESSMENT FORUMSM

New Treatments for Patients with Hepatitis C

Questions for Deliberation

March 10, 2014

Comparative *Clinical Effectiveness*

Example Question

- Is the evidence “**adequate**” to demonstrate that “**intervention A**” is equivalent or superior to “**comparator B**” for patients with “**condition X**”?
 1. **Yes**
 2. **No**

Comparative *Value* Example

Question

- If yes, what is the comparative value of “intervention A” vs. “comparator B”?

Low Value	Reasonable/ Comparable Value	High Value
1. Worse outcomes; Higher or equivalent cost	5. Worse outcomes; Lower cost	9. Comparable outcomes; Lower cost
2. Comparable outcomes; Higher cost	6. Comparable outcomes; Comparable cost	10. Promising but inconclusive evidence of better outcomes; Lower cost
3. Promising but inconclusive evidence of better outcomes; Higher cost	7. Promising but inconclusive evidence of better outcomes; Comparable cost	11. Better outcomes; Lower or comparable cost
4. Better outcomes; Too high a cost	8. Better outcomes; Reasonable higher cost	12. Better outcomes; Slightly higher cost

Practice Question

What is your favorite national park?

- 1. Acadia**
- 2. Denali**
- 3. Grand Canyon**
- 4. Haleakalā**
- 5. Yosemite**
- 6. Other**

Genotype 1: treatment-naïve, interferon eligible

See key tables pages 3, 4, 5.

Q1. Stipulate that SMV + PR and SOF + PR are superior to TEL + PR because of adequate evidence of equal to better SVR and fewer side effects.

1. Yes

2. No

Genotype 1: treatment-naïve, interferon eligible

See key tables pages 3, 4, 5.

Q1a. If yes, what is the comparative value of SMV + PR vs. TEL + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-naïve, interferon eligible

See key tables pages 3, 4, 5.

Q1b. If yes, what is the comparative value of SOF + PR vs. TEL + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-naïve, interferon eligible

See key tables pages 3, 4, 5.

Q2. Stipulate that the evidence is inadequate to distinguish between the clinical effectiveness of SOF + PR and SMV + PR.

1. Yes

2. No

Genotype 1: treatment-naïve, interferon ineligible
See key tables pages 3, 4, 5, and 6 (COSMOS).

Q3. Stipulate that SOF + R is superior to no treatment.

- 1. Yes**
- 2. No**

Genotype 1: treatment-naïve, interferon ineligible

See key tables pages 3, 4, 5, and 6 (COSMOS).

Q3a. If yes, what is the comparative value of SOF + R vs. no treatment?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-naïve, interferon ineligible
See key tables pages 3, 4, 5, and 6 (COSMOS).

**Q4. Is the evidence adequate to demonstrate that
SOF + SMV + R is superior to no treatment?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-naïve, interferon ineligible

See key tables pages 3, 4, 5, and 6 (COSMOS).

Q4a. If yes, what is the comparative value of SOF + SMV + R vs. no treatment?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-naïve, interferon ineligible
See key tables pages 3, 4, 5, and 6 (COSMOS).

**Q5. Is the evidence adequate to demonstrate that
SOF + SMV + R is equivalent or superior to
SOF + R?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-naïve, interferon ineligible

See key tables pages 3, 4, 5, and 6 (COSMOS).

Q5a. If yes, what is the comparative value of SOF + SMV + R vs. SOF + R?

Low Value	Reasonable/ Comparable Value	High Value
		6. Comparable outcomes; Lower cost
0. Comparable outcomes; Higher cost	3. Comparable outcomes; Comparable cost	7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

Q6. Stipulate that SMV + PR is superior to TEL + PR because of adequate evidence of equivalent SVR and fewer side effects.

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

Q6a. If yes, what is the comparative value of SMV + PR vs. TEL + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

**Q7. Is the evidence adequate to demonstrate that
SOF + PR is superior to TEL + PR?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

Q7a. If yes, what is the comparative value of SOF + PR vs. TEL + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

**Q8. Is the evidence adequate to demonstrate that
SOF + SMV + R is superior to TEL + PR?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

Q8a. If yes, what is the comparative value of SOF + SMV + R vs. TEL + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

**Q9. Is the evidence adequate to demonstrate that
SOF + SMV + R is superior to SMV + PR?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon eligible

See key tables pages 6, 7, 8.

Q9a. If yes, what is the comparative value of SOF + SMV + R vs. SMV + PR?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

Q10. Is the evidence adequate to demonstrate that SOF + R is superior to no treatment?

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

Q10a. If yes, what is the comparative value of SOF + R vs. no treatment?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

**Q11. Is the evidence adequate to demonstrate that
SOF + SMV + R is superior to no treatment?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

Q11a. If yes, what is the comparative value of SOF + SMV + R vs. no treatment?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

**Q12. Is the evidence adequate to demonstrate that
SOF + SMV + R is superior to SOF + R?**

- 1. Yes**
- 2. No**

Genotype 1: treatment-experienced, interferon ineligible

See key tables pages 6, 7, 8.

Q12a. If yes, what is the comparative value of SOF + SMV + R vs. SOF + R?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 2: treatment-naïve or treatment-experienced

See key tables pages 9, 10, 11, 12.

Q13. Stipulate that SOF + R is superior to PR for interferon eligible patients and that SOF + R is superior to no treatment for interferon ineligible patients.

- 1. Yes**
- 2. No**

Genotype 2: treatment-naïve or treatment-experienced

See key tables pages 9, 10, 11, 12.

Q13a. If yes, what is the comparative value of SOF + R vs. PR for interferon eligible patients?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 2: treatment-naïve or treatment-experienced

See key tables pages 9, 10, 11, 12.

Q13b. If yes, what is the comparative value of SOF + R vs. no treatment for interferon ineligible patients?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 3: treatment-naïve or treatment-experienced

See key tables pages 13, 14, 15, 16.

Q14. Stipulate that SOF + R is superior to PR for interferon eligible patients and that SOF + R is superior to no treatment for interferon ineligible patients.

- 1. Yes**
- 2. No**

Genotype 3: treatment-naïve or treatment-experienced

See key tables pages 13, 14, 15, 16.

Q14a. If yes, what is the comparative value of SOF + R vs. PR for interferon eligible patients?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost

Genotype 3: treatment-naïve or treatment-experienced

See key tables pages 13, 14, 15, 16.

Q14b. If yes, what is the comparative value of SOF + R vs. no treatment for interferon ineligible patients?

Low Value	Reasonable/ Comparable Value	High Value
		7. Promising but inconclusive evidence of better outcomes; Lower cost
1. Promising but inconclusive evidence of better outcomes; Higher cost	4. Promising but inconclusive evidence of better outcomes; Comparable cost	8. Better outcomes; Lower or comparable cost
2. Better outcomes; Too high a cost	5. Better outcomes; Reasonable higher cost	9. Better outcomes; Slightly higher cost