

Ethical Consideration Involving Employer Health Plan Drug Coverage and Treatment of Hepatitis C

Employers have a major stake in their health plans as it serves to protect and improve the health status of their employees. This in turn, promotes employee loyalty and productivity. The health plan also serves as a tool for attracting new employees. Concomitantly, the employer also has a duty to ensure the financial health of the company so as to return shareholder investment and generate growth or, at least, conserve current profitability. Every year, employers review their health benefit plans to determine the scope of drug coverage. They also have to decide whether they will take the risk of funding the plan themselves (self-insured coverage) or to purchase a plan from a commercial insurance company (underwritten coverage).

Prescription medication is an essential component in treating a plethora of diseases. Prescription drug coverage therefore, is often a standard benefit in an employer sponsored health plan. While health plan cost trends have moderated, pharmacy costs have outpaced inflation and wage growth by 300%.¹ As a result, prescription drug costs now constitute 21% of plan expenditures.²

Specialty drug/biotech medications have a disproportionate impact on health plan costs. While they comprise less than 1% of an employer's drug benefit coverage, they are projected to account for 35% of total 2017 prescription costs.³ One such specialty drug is the class of direct acting anti-virals ("DAAs"). These drugs are highly effective in curing chronic hepatitis C. This in turn, prevents the disease from precipitating liver failure, liver transplant, hepatic carcinoma and/or death. Unfortunately, DAAs are very expensive.

Employers face several decision points when addressing health plan coverage for chronic hepatitis C:

1. Hepatitis C progresses slowly, so should the company pay for treating but not curing chronic hepatitis C if this approach is less expensive than covering DAAs?
2. Should the company cover DAAs but set acuity standards that would need to be met before the employee would be eligible to be treated with DAAs?
3. Should the company set tenure standards for treatment eligibility so as to get a return on health plan investment?
4. Can the company set behavior standards for eligibility for treatment such as a requirement that the employee discontinue use of alcohol or injected opioids?

¹ Steven Miller, Employers Prepare for 2017 Drug Price Hikes, Society for Human Resource Management online article, <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/2017-drug-plan-cost-strategies.aspx>, accessed September 2017

² Op. cit.

³ Op. cit.

5. Does the company need to structure the pharmacy benefit plan to ensure that an employee can afford any cost-share for the drug?

What is acute versus chronic hepatitis C and who is at risk for it?

Hepatitis C is a viral infection that causes liver inflammation that can lead to serious liver damage (i.e. fibrosis and cirrhosis) as well as liver cancer (hepatic carcinoma) and death. It spreads through contaminated blood.⁴ There are two stages of hepatitis C infection – acute and chronic. The acute phase symptoms may take 1 – 3 months to appear after viral exposure and may include fever, fatigue, decreased appetite, nausea, vomiting, abdominal pain, dark urine, grey colored feces joint pain and jaundice.⁵ However up to 80% of people with acute hepatitis C will be asymptomatic and may never know they were infected.⁶ About 15% - 45% of infected people will spontaneously clear the virus within six months without any medical intervention⁷. Of those individuals who do not clear the virus, 55% - 85% will develop chronic hepatitis C.⁸ It is this chronic variant and its associated inflammation that can slowly destroy the liver. It is estimated that 15% - 30% of individuals with chronic hepatitis C will develop cirrhosis of the liver within 20 years.⁹

Treatment Options

In the early 2000's, the standard treatment regimen for chronic hepatitis C involved weekly injections of peglyated interferon along with daily oral doses of ribavirin. However, side effects associated with this regimen prevented many patients from completing treatment. However, in 2013, protease inhibitors were introduced. These drugs disrupted the ability of the virus to replicate (i.e. *direct acting anti-virals*) and were orally administered. They are well tolerated and easy to administer. However, they are expensive, ranging from approximately \$54,000 (Zepatier)¹⁰ to \$150,00 (Olysio)¹¹ for a 12-week regimen.

Employer Decision Points and Ethical Considerations

1. To buy or not to buy, that is the question.

⁴ Hepatitis C Overview, accessed through Mayo Clinic website, <http://www.mayoclinic.org/diseases-conditions/hepatitis-c/symptoms-causes/dxc-20207369>, accessed September 2017

⁵ Hepatitis fact sheet updated July 2017, World Health Organization, <http://www.WHO.int/mediacentre/factsheets/fs164/en/> accessed September 2017

⁶ Op. cit.

⁷ Op. cit.

⁸ Op. cit.

⁹ Op. cit.

¹⁰ Hepatitis C Online, drug summary for Zepatier, accessed through the University of Washington website, <https://www.hepatitisc.uw.edu/page/treatment/drugs/elbasvir-grazoprevir>, accessed January 2018

¹¹ Hepatitis C Online, drug summary for Olysio, accessed through the University of Washington website, <https://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug/drug-summary>, accessed January 2018

The first decision that management has to make, is whether or not to include DAAs in the organization's health plan coverage. Hepatitis C progresses slowly, so employees can lead normal productive lives while still having the disease. Management could therefore elect to offer medical coverage to treat the symptoms of the disease only while excluding some or all DAA coverage.

Utilitarianism principles would lead management to offer DAA coverage as it would optimize the interest/satisfaction levels for the greatest number of people. Specifically, it would reduce the chance of infection for family members, colleagues and the population at large which is clearly a widespread beneficial consequence. However, utilitarianism would also consider coverage from a more formal cost/benefit perspective. The average costs to treat, but not cure, hepatitis C in the U.S. is estimated to be \$64,490 over the course of the infected person's life.¹² Given that only one DDA falls below this cost, providing supportive medical care without use of a DAA is a practical alternative. The concept of marginal utility however, would shift the cost/benefit equation in the other direction. The intense need of an infected person to avoid further organ damage would override the potential cost savings from status quo medical care. Only the provision of DAAs offer cure and the avoidance of further health damage. Thus, this additional perspective would still lead management to adopt benefit plan coverage for DAAs.

Rights-based ethical principles would also require the employer to offer the coverage as it is the best option for cure. This theory asserts that individuals have inherent value requiring protection of their personhood and the opportunity to pursue their own interest. This theory in turn confers a positive duty on the employer to protect the inherent value of an infected employee. Thus, a cure best respects the infected person's autonomy, dignity and the opportunity for a normal life span.

As both sets of ethical principles arrive at the same conclusion, they are both equally preferable. Management should therefore provide DAA coverage. However, there is an underlying caveat to this conclusion. If the cost of including DAAs in the employee benefit plan would jeopardize the financial future of the company, management would be acting ethically to omit this coverage. This is because management has a duty to the other stakeholders (i.e. stockholders, owners, other employees, customers, etc.) to ensure the stability and/or growth of the company.

Once the decision to cover DAA has been made, management would face two options to implement the choice. Management could purchase an underwritten insurance plan from a commercial insurance carrier or

¹² Homie Razavi, Antione Elkhoury, Elamin Elbash, Chris Estes, Ken Pasini, Thierry Poynard & Ritesh Kuma, "Chronic Hepatitis C Virus Disease Burden and Costs in the United States", *Hepatology*, 2013, vol. 57: pp.2164-2170.

take on the full financial risk for the employee health plan by being “self-insured”. If management goes the commercial insurance route, the questions raised earlier in this analysis, such as setting acuity, tenure and behavior for DAA coverage, will largely be taken out of management’s hands. This is because the insurance company will determine the best way to structure DAA benefits to protect its own viability while providing the sought-after coverage. Commercial insurance coverage thus comports with both utilitarian and rights-based ethical principles as it optimizes general benefit and the interests of an infected individual.

A self-insured plan offers management the greatest flexibility in designing a benefit structure that can be customized to meet the specific needs of the company’s employees. A self-insured plan comports with utilitarian constructs as it can optimize cost-benefit in its design in order to best serve the needs of all employees. At the same time, a self-insured plan is in line with rights-based principles as the coverage offered can be tailored in a way to ensure individualized treatment that best promotes the wellbeing of the infected person. This option however, may not best serve the needs of the shareholder stakeholders as self-insured plans are wholly funded by the company up to the point that stop-loss¹³ coverage kicks in. In addition, a self-insured plan would require management to address the following additional ethical issues.

2. Should acuity standards apply before DAA coverage kicks in?

The level of hepatitis C damage on the liver is discernable either through biopsy or ultrasound. Theoretically, a damage threshold could be established that would trigger eligibility for a DAA treatment regimen. However, utilitarian principles would not support management in establishing such a trigger as it exposes the larger community (the greater good so to speak) to possible infection. On the other hand, the risk of infection is very small so this is not a strong argument for management to rely upon. Marginal utility provides a stronger utilitarian case given the priority need the infected person has to avoid permanent organ damage.

Rights-based principles would also overrule setting an acuity threshold as any arbitrary barrier to treatment would violate respect for the infected person’s autonomy. Choosing an acuity threshold sets up a false value scale that attempts to relate the degree of damage to the worthiness of the person to receive medical treatment. Rights-based principles clearly put forth that the inherent value of the person and their right to be treated with dignity and respect is not contingent on being deemed sick enough to earn treatment.

Once again, both sets of ethical principles arrive at the same conclusion and are equally preferable. Therefore, management should not require an acuity threshold.

¹³ Stop-loss coverage is purchased from reinsurance companies and is designed to cover losses above a certain threshold. For example, a self-insured plan may acquire stop-loss coverage that kicks in when a single claim exceeds \$200,000. If the actual claim totaled \$1 million, the self-insured plan would pay the first \$200, 000 and the stop-loss coverage would cover the remaining \$800,000.

3. Should an employee have to meet tenure standards before being eligible for DAA coverage?

Covering the costs of DDAs is expensive and the US labor force is highly mobile. An employer therefore has to consider the cost/benefit for providing treatment for employees who move on to a different company once cured. One way to recoup this investment is to require the employee to work for their present company for a set time period prior to treatment. Alternatively, the employee would be required to continue working at their present company for a defined period after treatment. If the employee left before the expiration of the period, they would be required to repay all or some of the treatment costs. Imposition of tenure standards would not necessarily violate utilitarian principles unless treatment delay causes deterioration in the employee's health status. In other words, as long as delay did not undercut marginal utility, tenure requirement would not violate utilitarian ethical principles. Tenure would also support the interest of the other stakeholders due to the continued productivity being provided by the employee. However, adequate infection control would need to be in place in order to ensure the safety of others.

Rights-based ethics would not support any tenure restrictions as would violate the autonomy of the individual. Tenure restrictions are arbitrary by nature and sets up a false scale that bases the right to treatment on a timeframe that is unrelated to the need of the individual's medical condition. In short, arbitrary standards cannot be given higher value than the inherent value of the individual.

In this case the ethical principles appear to be at odds with one another. Nevertheless, management should choose a rights-based approach and not impose any tenure requirements.

4. Should there be behavior eligibility standards in order to qualify for DAA treatment?

Employees with hepatitis C have compromised liver function. Alcohol consumption and use of illegal drugs can damage the liver further before treatment. This raises the question whether management can require an infected employee to conform with certain behaviors prior to treatment (i.e. abstinence from drug and alcohol use). Utilitarian principles would not bar the imposition of behavioral standards as the consequences of abstinence optimizes outcomes for both the individual and the company. The concept of marginal utility is also not compromised by asking an infected employee to act in a responsible manner.

Rights-based principles would probably not support this approach as it encroaches upon the individual's autonomy. A competent person is entitled to make decisions, even if they are poor ones. In addition, employers don't tie other behaviors to benefit entitlement. For example, a person can leave the hospital against medical advice and their insurance coverage will still pay the hospital bill.

In this instance, management would be better served by adopting the utilitarian approach. Companies have limited financial resources that they must spend prudently. Adopting behavior prerequisites that optimize

treatment outcomes both support the ultimate wellbeing of the employee and the financial health of the company.

5. Does the company need to structure the pharmacy benefit plan to ensure that an employee can afford to buy a DAA if needed?

Most pharmacy benefit plans require that the employee contribute to the purchase price of formulary drugs. Usually this cost sharing consists of a flat co-payment, a deductible amount and percentage (i.e. "co-insurance") of the drug's price. A typical such arrangement might require the employee to pay a deductible of \$2,000 and a co-insurance amount of 20%. This requirement is not a barrier if the cost of the drug is relatively low. However, given the costs of Zepatier or Olysio, the employee would have responsibility for \$12,800 and \$32,000 respectively. Few employees could afford such a large expense and may therefore forego obtaining the necessary medication.

Since such a price barrier undercuts the principles of providing DAAs coverage in the first place, management could pursue several options. First, management could leave the structure of the contribution amounts untouched but arrange a payment plan whereby the employee would pay off their share of the drug's costs over time (perhaps through payroll deduction). This scenario would comport with the utilitarian principle of marginal utility for the infected employee, while at the same time ensuring the financial solvency of the benefit plan which in turn benefits the other employees. However, this solution would not satisfy the tenets of rights-based ethical principles as it places a disproportionate financial burden on those employees who make lower wages.

The second option that management could pursue is to cap the employee's total amount of out-of-pocket expense. The residual cost of the drug would be passed onto the other employees in the form of higher insurance premiums in order to keep the health benefit plan solvent. This approach would mesh with utilitarian principles as it meets the marginal utility needs of the infected employee and spreads out the residual cost in such a way that still preserves the interest/satisfaction of the other employees. This solution is also in accord with rights-based ethical principles as the price point allows all employees to have equivalent access to the DAA. Thus, it respects the autonomy of the infected employee.

A third option that management could elect to follow would be to create a separate fund to cover the costs of DAAs. The fund would be underwritten directly from the company's profits. Out-of-pocket expense could be made very low which would ensure that the infected employee is able to purchase the necessary medication. However, this option would not be supported by utilitarian principles even though it offers marginal utility benefit to the infected employee. This is because the cost of the fund could endanger the financial underpinning of the company which in turn would not optimize the interests of the other

employees, stockholders and customers. Nevertheless, rights-based ethical principles would strongly support this option however, as it offers the lowest barrier to care and thus strongly respects the infected employee's autonomy.

Of the three scenarios above, the second option offers management the best ethical approach as it meets the principles of both utilitarianism and rights-based theories.

In summary, ethical principles were applied in this case study to determine whether a company should include DAAs in their employee benefit plan. Both utilitarianism and right-based principles supported this inclusion. The next decision management had to make was whether to purchase the coverage from an insurance company or self-fund the coverage. Again, both sets of principles found either option on par with the other. Self-insured coverage however, required additional considerations. Relying on ethical guidance as analyzed in the above sections, management would choose the following options:

- Management should reject using a sickness threshold before the employee would be eligible for a DAA treatment regimen. Both utilitarianism and right-based theories were in agreement on this decision.
- Management should follow a rights-based standard and would reject employment tenures for treatment eligibility. This is the preferable ethical course due to the higher need to respect the infected person's autonomy.
- Management should adopt a unitarian approach and require the employee to comply with certain behavior standards in order to qualify for a DAA treatment regimen. This is the preferable ethical course because it recognizes personal responsibility and the impact it has on the company and stakeholders.
- Lastly, management should ensure that infected employees can afford the DAA treatment regimen. Both utilitarianism and rights-based principles make option #2 the preferred plan design.