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LS Prime® Feature:
Medical Monitoring Expense

Did you know?

An ever increasing concern for life sciences companies is liability for medical monitoring claims. Claimants pursuing these claims seek to recover the costs of monitoring to detect a disease or condition *before claimants have manifested any symptoms.*

Suppose a company has issued a Class I Product Recall because the continued use of a product has been found to cause, or has the potential to cause, serious injury in some users. The subsequent recall announcements may spark an influx of claims from product users who have not yet experienced any bodily injury. These users claim that they could fall victim to such injury if they do not receive ongoing testing and monitoring to prevent the injury from occurring. The cost of such medical monitoring for a large number of product users can be significant. Products liability policies—even those crafted specifically for life sciences companies—will only cover the cost of medical monitoring if physical injury has already been caused by the product. This means that the costs associated with monitoring patients who have not yet been injured—but remain at risk—are excluded.

How is LS Prime® different?

As part of its standard products liability coverage for bodily injury, LS Prime® (a non-admitted policy) covers the cost of medical monitoring where accompanied by physical injury[1]. But unlike other products liability policies, LS Prime® stands out by incorporating into its policy medical monitoring expense in the *absence of physical injury, sickness or disease*. If a claim for such expenses is made as a result of a **Class I Product Recall**, LS Prime® provides the solution. Similar coverage is also provided through LS Prime® where medical monitoring in the absence of physical injury is sought in the clinical trial setting[2].

Who needs this coverage?

- Medical Device Manufacturer
- Medical Device Component Manufacturer
- Biotech/Pharmaceutical Manufacturer
- Contract Manufacturing Organization (CMO)
- Dietary Supplement Manufacturer
- Cosmetic Drug and Medical Food Manufacturers

How does this coverage work?

LS Prime® Coverage Part A, Subpart 2[3] addresses medical monitoring in the absence of physical injury, sickness or disease. Coverage can be triggered by a claim for medical monitoring expense as a result of a product that has been subject to a **Class I Product Recall**.

[1]Coverage A, Subpart 1 covers bodily injury.
[2]Coverage E, Subpart 4 covers medical monitoring expense in the clinical trial setting.
[3]Coverage A, Subpart 2 Medical Monitoring Expense in the Absence of Physical Injury, Sickness or Disease.

See reverse side for Claims Examples

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Medical Monitoring Expense Claims Examples

Mesh Patch: A surgical mesh patch used to treat hernias is implanted into several patients during a clinical trial. It is discovered that the recoil ring sewn into the patch can break causing serious injury and the trial is placed on hold. Patients implanted in the clinical trial with the patch do not have any physical injury but they need to have a CT scan every month to monitor the patch's integrity. The patients make a claim seeking damages to cover Medical Monitoring. LS Prime® addresses this cost.

Heart Drug: Patients are taking the drug to treat heart failure and abnormal heart rhythms. A **Class I Product Recall** is issued because, due to a manufacturing defect, the drug contains twice the amount of the active ingredient. This can cause kidney failure and other serious injury. While those on the drug have not yet had any physical injury, they make a claim for Medical Monitoring Expense since they will need continued medical care to monitor for any injuries. LS Prime® addresses this cost.

OTC (Over the Counter) Drug: A cough syrup brand is subject to a **Class I Product Recall** because the syrup contains Phenylpropanolamine (PPA). PPA has been found to increase the risk of stroke in patients that ingest it. Patients that have taken this brand of cough syrup are seeking damages for medical monitoring. While none of the patients have suffered a stroke, they will need continued medical attention to check for signs of a stroke. LS Prime® addresses this cost even though no patient has suffered a stroke.

Dietary Supplement: A patient, as a result of taking dietary supplements, has sustained severe damage to his liver. The damage was a result of an undeclared ingredient known to cause liver damage. The manufacturers and the distributors of the dietary supplement issue a **Class I Product Recall**. News of the recall reaches other product users and they make a claim for expenses needed to cover their continued medical monitoring. Even though they do not have any current signs of bodily injury they will need continued care to monitor for liver damage.