

CASE STUDY: UNIVERSAL COVERAGE OF LOW OSMOLAR CONTRAST MEDIA

SUMMARY

For years, the Centers for Medicare and Medicaid Services (CMS) declined to offer universal Medicare coverage for the use of low osmolar contrast media (LOCM) among Medicare beneficiaries. CMS maintained this policy for a decade without considering dramatic changes in computed tomography (CT) technology and several studies showing the clinical advantages of using LOCM compared to high osmolar contrast media (HOCM). LOCM is generally viewed at least as effective as HOCM with significantly fewer adverse reactions. This translates into higher quality of patient care and lower costs for treating minor or major reactions due to HOCM.

In January 2005, CMS finally adopted a new policy in response, in part, to longstanding lobbying efforts by physicians, including the American College of Radiology. CMS agreed to remove payment restrictions for LOCM, making the pharmaceutical universally available to all Medicare patients. CMS recognized that LOCM reduced the risk of complications (flushing, anxiety, nausea, and vomiting) and that its use had become standard practice among radiologists. The policy change has enhanced the quality of care for Medicare patients, while providing a more cost-effective coverage system for providers who no longer need to screen for high-risk patients.

POLICY

CMS based limited coverage of LOCM on five criteria that looked at whether the patient had: a history of previous severe adverse reactions; a history of asthma and allergy; significant cardiac dysfunction; generalized debilitation; and sickle cell disease. Discrepancies also existed in reimbursement policies between hospital and nonhospital settings. CMS paid for LOCM used in all CT performed with contrast and angiography for Medicare beneficiaries in the hospital outpatient setting, yet maintained limited reimbursement criteria for LOCM use on inpatients and patients treated in nonhospital settings.

LOW OSMOLAR CONTRAST MEDIA

Low osmolar contrast media is a pharmaceutical agent used in contrast-enhanced CT procedures, contrast-enhanced computed tomography angiography (CTA) procedures; diagnostic and interventional angiography; diagnostic cardiac catheterization and interventional procedures; contrast-enhanced X-ray procedures; and intrathecal procedures.

MISAPPLICATION OF EVIDENCE-BASED MEDICINE

CMS maintained this policy despite studies demonstrating the safety advantages of using LOCM compared to HOCM, especially among the elderly, which constitutes the Medicare population. CMS kept the policy even though the price differential between the two contrast agents had significantly decreased over the years.

- Two studies showed low osmolar dyes were better than high osmolar dyes at preventing adverse events. (*Wolf, et al*) (*Katayama, et al*) Patients experienced a lower rate of physiologic reactions (flushing, anxiety, nausea, vomiting) with LOCM relative to HOCM.
- One study found that the choice of dye (low ionic vs. high ionic) was itself a risk factor that could lead to an adverse event. (*Palmer*)
- Another study showed patients who were older than 60 years or had unstable angina were at a greater risk of having a severe reaction with HOCM and 3.5 times more likely to have a moderate reaction. The study found LOCM produced fewer hemodynamic and electrophysiologic changes during cardiac angiography. (*Steinberg, Moore, Powe, Gopalan, Davidoff, Litt, Graziano, Brinker.*)

- One study found patients were better able to tolerate LOCM during cardiac angiography compared with HOCM. Twenty-nine percent of those who received HOCM were treated for adverse events, compared with nine percent of patients who received nonionic agents. (*Barrett, Parfrey, Vavasour, O’Dea, Kent and Stone*)

CMS also selectively focused on segments of studies, while overlooking the overall positive conclusions that pointed to the safety of LOCM.

- Insurers cited studies that concluded that offering universal coverage of LOCM—although clinically safer for everyone—was not cost effective. Payers ignored the scientific data showing the LOCM were safer for all patients. Instead, payers developed an economically based policy that rationed LOCM to patients at highest risk, but did not fully reflect the risk criteria found in clinical studies. Patients frequently were not informed that a safer agent was available, even though published studies indicated that some patients may have willingly paid for LOCM to avoid adverse reactions.

CLINICAL IMPLICATIONS

CMS’s restrictive policy put patients, especially the elderly, at risk for adverse reactions by ignoring numerous scientific studies that clearly demonstrated the safety advantages of LOCM.

CMS maintained the policy even after the development power injectors—which came long after published studies of LOCM’s clinical safety—underscored the advantages of using LOCM. Today’s technology can take multiple scans of the body in seconds using preprogrammed power injectors that set the critical timing between contrast injection and scan acquisition. Patients must remain still during the scan acquisition, especially during CT angiography. Acquiring a high quality scan is difficult if patients can’t keep still due to nausea, anxiety, flushing or vomiting, which more likely occur with HOCM. That means patients must undergo a second scan, which is costly to providers and insurers, as well as stressful to patients.

Lastly, the policy placed a costly and unfair burden on physicians to provide the staff and resources needed to screen for high-risk patients, increasing the potential for malpractice claims.

CONCLUSION

CMS’s decision to provide universal coverage for LOCM demonstrates that physicians can bring about significant changes by working together and harnessing their resources. This case also underscores the need for physicians to look beyond an abstract or study summary and become familiar with the details of a study. Informed physicians can better counter arguments from payers or other policymakers who may focus on one part of a study where the results support their policy preferences. Another key factor is making sure that policies clearly distinguish conclusions based on scientific evidence versus conclusions based on economic factors.