



Department of Health

Medicaid Reimbursement of Synagis

Report 2008-S-153



Thomas P. DiNapoli

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State of New York Office of the State Comptroller

Division of State Government Accountability

October 15, 2009

Richard F. Daines, M.D.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

Dear Dr. Daines:

The Office of the State Comptroller is committed to helping State agencies, public authorities and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Department of Health, entitled Medicaid Reimbursement of Synagis. This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

*Office of the State Comptroller
Division of State Government Accountability*



State of New York Office of the State Comptroller

EXECUTIVE SUMMARY

Audit Objective

Our objective was to determine whether the Department of Health (Department) ensured that claims for Synagis were paid according to Department guidelines and controls.

Audit Results - Summary

Synagis is a prescription medication covered by Medicaid that helps to decrease the incidence of human respiratory syncytial virus (RSV) in children that were born prematurely, or diagnosed with serious respiratory conditions like congenital heart disease or chronic lung disease. Synagis is an expensive drug, costing, on average about \$2,000 monthly per recipient. The Department reimbursed pharmacies approximately \$146.5 million for Synagis for the three year period ending June 30, 2008.

The Department has established Synagis guidelines regarding the proper prescription and use of Synagis for Medicaid recipients. These usage guidelines, which are similar to guidelines set by other states and the manufacturer, are not meant to prohibit payments for prescriptions beyond the guideline amounts. Rather, the guidelines are intended to inform providers regarding the expected use of this drug and serve as a norm for prescribing practices. The guidelines indicate that Synagis should be given to children under two years old at the beginning of an RSV season and that no more than five monthly doses per child will be prescribed during the RSV season. The Department has also established limits for the refilling of a Synagis prescription. Generally, a prescription cannot be dispensed and billed until 21 days have elapsed from the prior Synagis prescription being dispensed.

During our audit, we found that the Department has not established edits in the eMedNY system to detect for further review payments that do not comply with Department guidelines. During the period July 1, 2005 to June 30, 2008, we identified approximately \$29.7 million of Medicaid paid claims for Synagis that did not meet Department guidelines. This resulted in potentially unneeded costs to the Medicaid program as follows:

- Claims outside of the RSV season - \$17.9 million
- Claims for children over the age of two at the start of the season - \$3.3 million
- Claims for more than five doses in one RSV season - \$6.2 million
- Early filling of prescriptions - \$ 2.3 million

We recommend the Department develop or improve controls on the Medicaid claims processing system to ensure compliance with Synagis guidelines and existing controls.

This report, dated October 15, 2009, is available on our website at: <http://www.osc.state.ny.us>.

Add or update your mailing list address by contacting us at: (518) 474-3271 or

Office of the State Comptroller

Division of State Government Accountability

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Albany, NY 12236

Introduction

Background

The New York State Medicaid program (Medicaid) provides medical services, including pharmacy services, to low-income individuals who meet program eligibility requirements. The Department of Health (Department) must provide eligible individuals with adequate access to prescription drugs in a cost efficient manner. Synagis, a prescription medication covered by Medicaid, helps to decrease the incidence of human respiratory syncytial virus (RSV) in infants that were born prematurely, or diagnosed with serious respiratory conditions like congenital heart disease or chronic lung disease. In the United States, RSV infections regularly peak in the winter months and often can lead to lower respiratory tract infections and, in more severe cases, pneumonia, in infants. RSV occurs in New York primarily between November and April, and is one of the leading causes of hospitalization for children under one year old.

Synagis typically is given in monthly injections throughout the RSV season at a dosage of fifteen milligrams for every kilogram of bodyweight. Synagis is an expensive drug, costing approximately \$2,000 a month for each individual. Medicaid paid approximately \$146.5 million in claims for Synagis during the period July 1, 2005 through June 30, 2008. The Department has issued guidelines for the prescription and use of Synagis in the Medicaid program. These guidelines closely reflect the guidance provided by other states and the manufacturer. In addition to these guidelines, the Department has established guidelines for pharmacies to follow when filling Synagis prescriptions.

Audit Scope and Methodology

We audited to determine whether the Department ensured that claims for Synagis were paid according to Department guidelines and controls. Our audit covered the period July 1, 2005 to June 30, 2008.

To accomplish our objectives we reviewed the Department's guidelines and controls for Synagis use. We used computer assisted audit techniques to review all Synagis claims during our audit period to identify claims that did not meet Department guidelines. We met with Department officials as well as pharmacy officials and physicians to understand appropriate Synagis use. We also researched other states' guidelines, as well as, the manufacturer's recommendations for using Synagis.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit

objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds and other payments. In addition, the Comptroller appoints members to certain boards, commissions and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

Authority The audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

Reporting Requirements We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in it. Department officials agreed with our report's recommendations and indicated the steps that will be taken to implement them. In addition, pursuant to the Department's comments, we made certain revisions to the report as noted in our State Comptroller's Comments.

Contributors to the Report Major contributors to this report include Steve Sossei, Sheila Emminger, Paul Alois, Brian Krawiecki, and Frank Commisso.

Audit Findings and Recommendations

Compliance with Guidelines and Controls

To help ensure that Synagis is prescribed appropriately, the Department has established guidelines for its use. The Department guidelines state that Synagis should be given to children less than two years of age at the beginning of an RSV season, and that no more than five monthly doses should be received by the child during the RSV season. In addition, the Department has established guidelines that limit a pharmacy's ability to dispense and bill Medicaid for a new monthly dose within 21 days of the prior dose of Synagis being dispensed.

Based on our analysis of Synagis claims paid to pharmacies during our audit period, we found that Department guidelines are not followed, and that adequate controls have not been installed in the Department's eMedNY system, the system used to adjudicate Medicaid claims, to identify potential overuse of this expensive drug. During the period July 1, 2005 to June 30, 2008, we identified, through data analysis, that approximately \$29.7 million of the \$146.5 million in Medicaid paid claims for Synagis were non-compliant with Department guidelines. In addition, the Department has no procedures to investigate the non-compliant claims prior to payment.

The Department's guidelines define the RSV season in New York as November to April of each year. However, during our audit period, we found the Department reimbursed pharmacies approximately \$17.9 million for Synagis claims outside of the RSV season, and the Department did not detect nor investigate the reasons for this drug usage. Synagis claims outside of the normal RSV season were allowed to be paid because the eMedNY system does not have the edit controls necessary to detect or prevent paying claims before November or after April. We found nearly all out-of-season claims occurred in September or October, the two months immediately preceding the RSV season.

Department guidelines also state that prescriptions should be limited to children less than two years of age at the start of the RSV season. Children who turn two years old during the RSV season are allowed to continue treatments without question throughout the remainder of the RSV season, if they had started treatment before they turned two. However, we identified \$3.3 million in pharmacy claims for children who started receiving Synagis after they had already turned two years old. Again, Medicaid paid these claims because eMedNY lacked an edit to prevent the payment, and the Department did nothing to identify and investigate these claims prior to payment.

Prior to August 2007, the Department had put in place edits to prevent the payment of claims for children who were 4 years or older. In August 2007, the Department tightened the control to prevent claims for children 3 years or older at the time of service. Department officials explained the claims processing system needs to be able to accept legitimate claims for those children who turn two during the course of an RSV season. However, the control in place currently also allows claims for children who inappropriately start receiving Synagis after they have turned two years old. Therefore, while the Department has established guidelines for the prescription of Synagis, it has not established adequate controls in eMedNY to identify potential overuse of Synagis.

Although the Department developed guidelines pertaining to the number of doses a child should receive during one RSV season, the Department has not established any edits in eMedNY to detect and flag the occurrence of these transactions. According to Department guidelines, children should receive no more than five monthly doses during the RSV season. However, through our analysis we identified children for whom Medicaid paid more than five monthly doses in a RSV season. We identified approximately \$6.2 million for claims in excess of the five monthly doses allowed by Department guidelines. These extra doses occurred because the eMedNY system does not have an edit in place to detect and prevent paying claims for greater than five doses for a single child. There were a variety of situations that may occur which could result in an extra dose being properly prescribed and paid for by Medicaid. For example, we identified one instance in which the child switched physicians and obtained a prescription to go to another pharmacy. Since the first pharmacy wasn't notified, they continued to fill the prescription resulting in additional costs to the Medicaid program. However, these situations are not identified and investigated by the Department.

The Department has also issued guidelines that state a new Synagis prescription can not be filled (and be paid for by Medicaid) within 21 days of the prior prescription. During our audit period, the Department's early filling controls were limited to refilling an existing prescription, and did not take into account that the children may change doctors and get a new prescription. We applied the Department's 21 day guideline to Synagis claims during our audit period and found that the Department paid \$2.3 million in claims for Synagis doses less than 21 days apart. Early filling of a prescription can result in extra doses and potentially unneeded costs to the Medicaid program. Beginning in October 2008, the Department modified its existing control to look at refills and other prescriptions for the same drug. Pharmacists may override the control, but must indicate a specific reason for doing so.

The Department has routinely informed pharmacies and other medical professionals of the guidelines and changes to the Medicaid program by a monthly Medicaid update. Recently, the Department has established a prescriber education program, which is used to communicate with prescribers regarding the Department's expectations regarding the prescribing of certain drugs. Synagis is one of the first drugs being addressed in this program. Department officials indicate that they have discussed the appropriate use of Synagis with over 200 prescribers. We did not evaluate this program as it was not operational during the scope of this audit.

In addition, in their response to our draft report, Department officials noted that work has been initiated on changes (to the eMedNY system) providing for the prior authorization of Synagis when prescribed outside of the formal parameters established for its normal use. Officials further noted, however, that current law limits the Department's ability to deny the payment of claims for Synagis, and consequently, a physician's decision to prescribe Synagis outside of the parameters for normal use will be honored so long as sufficient clinical justification for such use is provided.

Recommendations

1. Take steps to ensure compliance with Department issued guidelines relating to duration of the RSV season, age of the individual receiving Synagis, and the number of doses an individual receives.
2. Monitor the early refill edit to ensure it is working as intended and that it is not being excessively overridden.
3. Continue to use the newly developed prescriber education program to communicate with prescribers regarding Synagis guidelines and controls.

Agency Comments



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

August 5, 2009

Mr. Brian E. Mason, Audit Manager
Office of the State Comptroller
Division of State Government Accountability
110 State Street, 11th Floor
Albany, New York 12236

Dear Mr. Mason:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's draft audit report 2008-S-153 on "Medicaid Reimbursement of Synagis."

Thank you for the opportunity to comment.

Sincerely,

Wendy E. Saunders
Executive Deputy Commissioner

Enclosure

cc: James Sheehan
Robert W. Reed
Deborah Bachrach
Nicholas Meister
Steve Abbott

Irene Myron
Gail Kerker
Ron Farrell
Mary Elwell

Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2008-S-153 on
“Medicaid Reimbursement of Synagis”

The following are the Department of Health’s (Department) comments in response to the Office of the State Comptroller’s (OSC) draft audit report 2008-S-153 on “Medicaid Reimbursement of Synagis,” including general comments followed by responses to the specific recommendations contained in the report.

General Comments:

The draft audit report states under Audit Findings and Recommendations, “In part, because Synagis is a relatively expensive drug (costing about \$2,000 a month, on average, per recipient), the Department has established guidelines for the prescription of Synagis.” To clarify, the guidelines were established as a means of assuring appropriate prescribing.

*
Comment
1

Additionally, the draft report fails to address the statutory landscape, as the absence of enabling legislation curbs the Department’s ability to deny claims, even where there is a conflict with, or a failure to meet, established medical guidelines. New York State law, including Section 3-a of Part Z2 of Chapter 62 of the laws of 2003, PHL 272(4) and PHL 274(7), restricts the Department’s ability to prior authorize prescription drugs under the Medicaid program. Only drugs that meet certain program requirements established by legislation can be prior authorized. One such program is the Clinical Drug Review Program (CDRP). For a drug to be included in the CDRP, the Medicaid Pharmacy and Therapeutics (P&T) Committee must recommend and approve its inclusion. And even if approved by the P&T Committee, under current State law, the prescriber can override the Department’s medical necessity determination, including where the drug’s use is inconsistent with clinical guidelines. Proposed changes in statute that would permit CDRP drugs to be denied absence evidence of medical necessity have been rejected by the legislature in the past.

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Comment
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The Department presented Synagis to the P&T Committee on February 20, 2008, for inclusion in the Medicaid CDRP. However, the Committee determined there was insufficient information at that time to recommend its inclusion, prohibiting the Department from using prior authorization to control utilization.

The Department again presented Synagis to the P&T Committee on April 24, 2009, at which time the Committee unanimously recommended its inclusion in the CDRP. The Committee further recommended that the following question be asked in the prior authorization process for utilization outside the Respiratory Syncytial Virus (RSV) season and for children over two years of age at the onset of the RSV season: “What clinical information supports the use of palivizumab (Synagis) for this patient outside the FDA approved clinical indications or American Academy of Pediatric (AAP) guidelines?” The Committee additionally recognized the RSV season in New York State as mid-October-through the end of March, and asked that the Department be mindful of and responsive to changes in the onset and offset of the season.

* See State Comptroller’s Comment on page 19.

The Commissioner of Health has approved the P&T Committee's recommendation, and the Department has initiated work on systems and program changes needed to implement prior authorization by October 2009. However, it is important to recognize that the prescriber's decision will continue to prevail, even if the drug's use does not meet approved FDA indications or AAP guidelines, because the existing legislation prohibits the Department from denying these claims.

The following links contain further information on the P&T Committee recommendations: http://www.health.state.ny.us/health_care/medicaid/program/ptcommittee/meetings/2008/02/ptsummary02-20-08.htm and http://www.health.state.ny.us/health_care/medicaid/program/ptcommittee/meetings/2009/04/ptsummary04-24-09.htm.

Recommendation #1:

Take steps to ensure compliance with Department issued guidelines relating to duration of the RSV season, age of the individual receiving Synagis, and the number of doses an individual receives.

Response #1:

The Department agrees and will take steps to ensure compliance by prior authorizing Synagis outside the general RSV season and for children over two years of age at the onset of the RSV season, as recommended by the P&T Committee and approved by the Commissioner of Health. This is expected to result in an overall reduction in the number of doses an individual receives.

It is relevant to note that the AAP guidelines for Synagis are expected to be updated sometime this year, which may necessitate further P&T Committee review and recommendations.

Recommendation #2:

Monitor the early refill edit to ensure it is working as intended and that it is not being excessively overridden.

Response 2:

The Department agrees and will monitor the early refill edit to ensure it is working as intended and is not excessively overridden.

Recommendation #3:

Continue to use the newly developed prescriber education program to communicate with prescribers regarding Synagis guidelines and controls.

Response #3:

The Department agrees and will continue to use its prescriber education program to communicate with prescribers regarding Synagis guidelines and controls.

State Comptroller's Comments

1. We have amended our report to note that the guidelines were established to help ensure that Synagis is prescribed appropriately.
2. We have amended our report to note that there are limitations on the Department's ability to deny claims for Synagis.