Pediatric/Adolescent Gastroesophageal Reflux Association, Inc.

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Restricting Insurance Coverage for Children with GERD

PAGER members report frequent problems with access to the treatments their children need. This can take the form of insurance denial of medical formulas, restricted access to the most appropriate medications, requirement of unnecessary testing, lack of dental care, restricted access to the most experienced specialists, etc.

The following information is provided to assist insurance providers in making appropriate decisions regarding access to treatment for children with GER.

Policy Statements Attached:

- Background
- Medical Formulas
- Medications and other treatments
- Testing
- Dental Issues
- Preauthorization
- Referrals to specialists
- Access to case coordination
- Coverage of positioning equipment
- Respite Care
- Feeding programs

[PAGER Association does not advocate for availability of specific brands. We advocate for the availability of all products so that doctors have the freedom to choose the best treatment plan for a given child. GERD in children is NOT homogeneous as it is in adults. It has many causes and many appropriate treatments.]

Background

Gastroesophageal reflux (GER/GERD) is a common disease that adults often consider trivial. But in children, it can be a very serious medical problem with long term health consequences. Children are more prone to apnea from reflux and this is one of the common causes of SIDS and near-miss SIDS events also knows as Apparent Life Threatening Events (ALTEs). Children with GERD may develop asthma, bronchitis, croup, or pneumonia from reflux. They can develop ear infections or ear congestions which compromise their hearing and put them at risk for learning delays. Children with GERD often have extreme trouble gaining weight which can permanently compromise their growth, brain development and immunity.

In addition to medical problems, GERD in children can lead to social and behavioral issues. GERD in adults causes excruciating chest pain which leads tens of thousands of them to emergency rooms each year. A child who experiences the pain of chronic GERD can become frustrated, disruptive, angry, destructive or depressed. They often have trouble sleeping and learning. They may become fearful of food and so selective about foods that their nutrition is compromised. The increase in the willingness of physicians to treat GERD is being driven partially by the recognition of borderline malnutrition as a serious issue.

Treatment of GERD is improving but still far from foolproof. This is demonstrated by the number of patients who are eager to try every new medication, surgery or alternative treatment in an attempt to fully control their symptoms and improve their quality of life.

GERD in children may be very obvious and diagnosable just from observation or it may take considerable clinical skill combined with a high degree of awareness of the many and varied ways the disease can present. There is often an alarming delay in receiving a diagnosis even after the child has significant complications. Many PAGER members report transferring to a second or third pediatrician in an attempt to find out what is causing their child's clear suffering. The dearth of pediatric gastroenterologists in the US means an additional delay of 3-8 weeks to get an intake appointment for those children whose pediatricians refer them on to such a specialist. Any delay in diagnosis can mean a much longer treatment period, particularly if the child develops esophagitis, asthma or feeding issues which can be refractory to treatment.

With adults, lifestyle is often a contributing factor in the development of GERD. In children, it is uncommon for obesity, alcohol, tobacco, spicy foods or fried foods to be a significant factor. In fact, nearly all children with GERD will self select against foods and activities that exacerbate their GERD, to the point where children in severe pain will simply stop eating altogether. With the exception of a few infants who eat too fast and too much, children's actions are not likely to contribute to developing GERD. Doctors are aware of this and counsel small frequent meals for children with GERD. Parents are not requesting expensive medications or specialists in lieu of adopting a healthier lifestyle for their child.

PAGER Association's biggest gift to medicine has been to shift the paradigm to thinking about pediatric GERD as having multiple causes. The science is just recently starting to catch up to our gut instincts.

PAGER Association initiated the first study of inherited GERD and the establishment laughed. This idea is now completely accepted and we have tracked the gene to a small section of Chromosome 13.

Doctors are now starting to peel out several other causes of GERD in children. Lactose intolerance symptoms are almost identical to GERD. Protein intolerance is another cause which is rapidly becoming a hot topic in gastroenterology. Eosinophilic gastroenteritis is a subform of protein intolerance which is a subform of GERD. Gut signaling issues can cause dysmotility which causes GERD. This is THE hot topic in neurogastroenterology and one we have been floating for years. We hope these discoveries lead to research on how brain immaturity in newborns can cause GERD. Next on our list is to pull out a form of pediatric GERD caused by autonomic instability.

While GERD in adults is largely related to lifestyle and age, GERD in children probably has at least five distinct causes that are just gaining recognition as potentially separate entities. This means the diagnosis and treatment of children with GERD may differ significantly from the diagnosis and treatment of children with GERD is changing rapidly. Some are treated with diet manipulation or high tech formulas, some are treated by reducing or eliminating acid, some are treated with medicines that improve gut motility.

Medical Formulas

Treatment of children with GERD often involves extreme diet manipulation far beyond the avoidance of GERD triggers commonly prescribed for adults. It is suspected that many cases of pediatric GERD are actually food sensitivities, allergies, protein intolerance, or other food intolerances masquerading as GERD. Because the symptom patterns of these conditions overlap dramatically and tests are not particularly accurate on children, trials of treatment are necessary to tease out the proper diagnosis. For a child who requires a special food, eating normal foods can cause violent vomiting, chronic or nearly constant regurgitation, erosions and ulcers of the esophagus, serious pain, poor weight gain or weight loss, and extreme eating disorders that are very expensive to treat.

Allergy and protein intolerance *experts* are now urging pediatricians to try extensively hydrolysed infant formulas (available at grocery stores). In many cases, use of these special formulas can reduce the GERD symptoms dramatically within days. There is a great deal of difference in the ingredients in these formulas and brand switching can make a dramatic difference in symptom reduction as well as indicating to the physician which ingredients are likely to be the culprit for an individual child. The studies to prove this have not been conducted yet.

For children who show partial but inadequate response to extensively hydrolysed formulas, amino acid based formulas, also known as elemental formulas, should be tried. Elemental formulas are very high tech medical foods developed by NASA and made from raw amino acids and vitamins. They contain no whole proteins so they are quite hypoallergenic and are available only by prescription. Their use for several weeks can produce dramatic results in terms of weigh gain, reduced vomiting and reduced pain. Often the child can be weaned onto regular foods after a year or two on a diet consisting of these hypoallergenic medical formulas and a very highly restricted list of table foods. Parents and doctors are reluctant to use these medical foods because compliance and taste are frequent problems so overuse and abuse are highly unlikely.

The out of pocket costs of these formulas can be several hundred dollars per month and waiting for reimbursement may not be feasible for many families. Many of the formulas need to be special ordered which already causes delays.

It is common practice for insurance companies to decline coverage for medical foods unless they are fed enterally (by tube). This may tempt the doctors and parents to forgo oral feeds in order to get needed nutrition. Pump feeding in these instances is short sighted and can lead to more expensive health care needs in the long term. Children who are on long-term pump feedings *exclusively* may forget how to eat and require an in-patient feeding program to wean them from tube feedings. It is almost always preferable to have the child taking any oral feedings that can be tolerated at that moment. Tolerance of oral feeds may wax and wane and should be driven by the child's needs, not insurance coverage.

Recommendation:
PAGER strongly encourages *direct* coverage for all brands of special formulas for children with GERD both as a diagnostic tool and on a long-term basis for enteral and oral feeding.

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Medication and other treatments

Because GERD can have such serious consequences in children, it is common for their physicians to use the strongest medications for initial symptom control and 'step down' to the less expensive medications for maintenance. In adults, 'step up' therapy is common, but there are many instances where a delay in fully controlling the symptoms of GERD in children can have a devastating effect. For example, a child who is reaching six months of age and still experiences significant pain from esophagitis when swallowing will begin to understand that food causes pain and will "self treat" the pain by simply refusing to eat at all. The resulting food aversions can result in tens of thousands of dollars in hospitalizations and feeding clinics that would not have been necessary if the GERD pain was treated promptly and effectively.

The most important factor in finding an effective medication for a given child is the ability of the parents to get the medicine into the child. No medication works if the child can't or won't take it. Babies and children under age 8 generally can't swallow tablets or capsules. Several common medications for acid reflux are only available in pill form. Some may be compounded into a suspension and specially flavored to cover the nasty taste of the baking soda-based compounding liquid. Others are not compoundable. Compounding results in an additional pharmacy charge and the bottle is typically only stable for about 2 weeks. Some pharmacies give parents the mixing kits and let them do the compounding at home if they are unable to travel to a pharmacy to get refills every two weeks. Solutabs are wonderful but only available in one brand of PPI. We understand that a skin patch is being developed to dose PPIs.

There are several brands of H2RA acid reducers and several brands of proton pump inhibitors, but the brands are not fully interchangeable. One child may find that one brand of medication is wonderfully effective, but a very similar chemical in another brand of the same class is completely useless. There are currently three motility medications and they are chemically unrelated and work in completely different ways. It may take several tries to find out which medication works best. While statistics may show that one brand is slightly more effective, an individual child is not a statistic and can't be treated as such. Brand to brand studies in children have not been conducted yet. We expect them to show quite idiosyncratic reactions.

Another factor which impacts the use of medications is the inert ingredients. Several common medications for reflux contain lactose or food colorings which make them impossible for many children to tolerate. They throw up more if given a medication with inert ingredients that they are allergic to or intolerant of. Even worse is the addition of alcohol to one of the commercially prepared suspensions. Zantac liquid, which is commonly used for babies, contains a significant amount of alcohol. Parents have complained for years that their children appear drunk or appear to crave this medication which tastes disgusting. A new preparation without alcohol is not yet widely available. A recent study http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10638585&dopt=Abstract demonstrated that ranitidine and alcohol taken together can make adults very drunk. PAGER volunteers routinely suggest that parents consider having ranitidine custom compounded to avoid the alcohol in the commercial pediatric formulation.

New studies show that children's livers are more efficient than those of adults and they consequently clear some drugs from their systems too quickly. Individual children may require extraordinarily high doses of medication per body weight or a daily total that is divided into many doses.

Although many GERD medications are being tested on children, many are not yet approved. It is certainly common for a doctor to prescribe a medication "off label," but it seems unwise for doctors to be forced to prescribe a drug for children that is not fully tested in that population.

Reglan (metoclopramide) is a drug often used to treat patients with GERD. Metaclopramide is a neuroleptic in the same category as Thorazine and other drugs to treat schizophrenia. All neuroleptics can and do cause serious, and permanent side effects called Tardive Dyskinesia. The use of metoclopramide in gastroenterology is of particular concern because gastroenterologists do not receive the special training necessary to spot the early and more reversible side effects before the more serious and potentially permanent side effects take hold. (The side effects mimic Tourette's Syndrome or Parkison's.) The use of metoclopramide in pediatrics is of even more concern because the side effects are even more difficult to spot in children. There is a lethal variation of the side effects (Neuroleptic Malignant Syndrome) that would be easier to miss in a child. The American Psychiatric Association recommends that its members obtain informed consent before prescribing any

neuroleptics, including metoclopramide. PAGER staff recently wrote a review article about Tardive Dyskinesia. It is available on our web site at www.reflux.org. (See Reading Room – Advanced Topics)

There are a number of other medications for GERD that are underutilized. Carafate (sucralfate) is not commonly used in the United States yet it can have good results for some children. Many types of motility medications are unavailable in the US and many more are in development.

Surgical treatments for GERD are advancing rapidly. Parents, gastroenterologists and surgeons need to be free from financial constraint to choose the most appropriate surgical treatments as each has distinct advantages and disadvantages for particular patients. An open surgery is typically cheaper but the recovery time is significantly higher. Some surgeons do laparoscopic procedures and others do not. Surgeons around the country have developed different styles of fundoplications. The newer intraluminal techniques are not appropriate for all patients nor are they available in all parts of the country.

We are very interested in the new gastric pacemaker technology as a significant number of our members are suffering from drastically delayed emptying. Installation of a gastric pacemaker is easily accomplished, but if the stimulation is not balanced correctly, the results will be disastrous and have given this procedure a bad reputation. If the stimulation is correct for the patient, relief of nausea, vomiting, reflux and delayed emptying is instantaneous. One doctor in the US is using the device on patients for just a few days to judge efficacy before proceeding with a surgical implantation.

Recommendations:
Access to the most powerful drugs should not be limited to patients who have failed on less expensive medications. All formulations should be available and covered fully. Premixed compounds should available every two weeks from a pharmacy that is convenient for the family rather than by mail or from a specific pharmacy. Mixing kits should be available and covered if this offers the best compliance for the family. All brands, formulations and custom compounds should be available and fully covered. Doctors should be allowed to dose and combine medications as needed. Informed consent should be required before using metoclopramide. Nontraditional medications should be made available if the physician can justify the need to try them, even if they need to be imported. If surgical intervention is necessary, patients may need access to a specialist outside their geographic area if a particular technique is recommended.

PAGER suggests a pediatric medication carve-out on the grounds of fragility, idiosyncratic reactions, disease heterogeneity, and formulation problems

Please see the statement on Preauthorization for additional information relevant to medication

Testing

Testing for GERD is not simple or straightforward. Many of the tests conducted on children with symptoms of GERD, are not tests for GERD, they are tests to rule out other diseases with similar symptoms. The tests for GERD can be difficult to interpret and vary somewhat by operator or software package. To complicate matters in pediatrics, the tests for GERD have not been performed on healthy children due to ethics. This means full validation of the test criteria and results is not possible.

Testing may be useful in confusing cases or when a child doesn't respond to treatment, but using a trial of treatment as a diagnostic tool is extraordinarily common and practical. In addition to producing unclear results, testing of children may be cruel even it is not invasive. Even a "simple" barium swallow is difficult in a child who dislikes the taste of chalk and the contrast medium may have to be given by nasogastric tube. A scintigraphy scan may show delayed stomach emptying, but this information is often available through parent observations without the need to strap a screaming child to an X-ray table for over an hour. Endoscopies on a child may not show esophagitis despite crystal clear clinical signs of esophageal pain because pain and damage do not correlate cleanly. It is well documented that some patients experience excruciating pain from reflux that appears trivial on a pH probe.

Recommendation:
Children who have clear symptoms of GERD should not have treatment withheld pending testing.

Because some of the testing is so traumatic, care should be taken to use the services of a child life specialist and appropriate sedation such as Valium lollipops should always be made available. In addition, children who are prone to choking may need to have endoscopies performed under general anesthesia to protect their airway. A pH probe is most accurate if the child has a normal activity level and the device is taken home overnight. Elbow splints are available to prevent small children from removing the nasal tubing.

Recommendation:
Appropriate devices, setting, sedation, analgesia, amnesiacs and anesthesia should be covered as part of testing.

Dental issues

One of the most insidious and unrecognized consequences of poorly managed GERD is tooth enamel erosion. Pediatric dentists are just starting to receive special training in the recognition of damage patterns that indicate that a healthy-appearing child needs to be treated for GERD. Unfortunately, GERD may not be recognized until extensive damage has occurred. This damage looks very similar to baby-bottle-mouth and is often mis-diagnosed as such. If mild enamel erosion is not recognized and treated early, the resulting erosion of the tooth can progress amazingly rapidly and teeth may need to be extracted just three months after a check up in which no trouble is noted.

Dentists can apply fluoride treatments or sealants to minimize the acid damage although sealants may lift if the acid seeps under them and may need to be reapplied. Some children with GERD require multiple root canals and caps. Even preschoolers and infants may sometimes require extensive rebuilding of deciduous teeth. These procedures must often be conducted under general anesthesia in a hospital to guard the child's airway.

In some states, only metal caps are covered by insurance which subjects the child to ridicule and borders on child abuse.

Recommendation:

The cost of root canals, natural color caps, additional monitoring, preventive treatments, quick access to treatment, and appropriate anesthesia for children with GERD need to be fully covered.

Preauthorization

Children with GERD are often the most high need children in the medical practice. They place an enormous burden on their parents and their doctors. They require frequent medical visits, many phone consultations, and sometimes weekly medication adjustments to keep them as healthy as possible and reduce the risk of long term and very expensive consequences such as asthma, food refusal or esophageal cancer which has a very dismal cure rate.

The mothers of these children can seldom hold an outside job due to extreme stress and sleep deprivation. Safe childcare is nearly impossible to find for a child who cries and vomits all day and many of our parents receive little respite care even from family members. These children often wake several times each night shrieking in pain and it can take an hour to console them.

Exact numbers are not available, but it is believed that 5-8% of otherwise healthy children have significant symptoms of GERD. This means that establishing separate procedures such as preauthorizations can easily overwhelm an insurance system. Adding preauthorization requirements or other hoops for parents and doctors to jump through can easily overwhelm the caregivers and compromise the child's health.

See also the statement about referrals to specialists – the dearth of pediatric gastroenterologists means that they are already overwhelmed and there is a significant delay (2-4 months) for an intake appointment.

Recommendation:
Preauthorization and similar requirements should be avoided for children with GERD.

Referral to Specialist

The level of skill in treating GERD varies dramatically among pediatricians and family practice physicians. Some are well versed in GERD and are comfortable treating a child whose symptoms are clearly indicative of GERD. Some are even comfortable treating GERD with significant complications and do a good job. Unfortunately, GERD treatment has only recently been incorporated into medical training curricula. This means that older physicians may not feel comfortable treating GERD unless they have completed continuing education on the topic.

Access to a specialist is often delayed for many weeks because there are not enough pediatric subspecialists. In some areas, pediatric gastroenterologists are conducting seminars for primary care physicians to get them more comfortable treating uncomplicated GERD and *reduce* the number of referrals for mild to moderate GERD. In addition, some other subspecialists such as pediatric pulmonologists and pediatric otolaryngologists have extensive training in the treatment of GERD and may not bother referring the patient to a gastroenterologist.

GERD is not a single disease and some specialists have more experience with different presentations of this complex condition. Unfortunately, there are even a number of pediatric gastroenterologists whose treatment of GERD is not current or sufficiently broad to allow them to effectively treat all children with all types of GERD. Some are reluctant to use the newer medications and others are still making extensive use of drugs such as Reglan (metoclopramide) and Donnatol (belladonna). It is not uncommon for a child with severe GERD to see three or four gastroenterologists before settling on one who is successful in resolving the majority of their symptoms.

Recommendation:
Access to a subspecialist or multiple subspecialists should be neither denied nor required.

Case coordination by pediatrician

Some neurologically normal children with GERD are under the care of more than five doctors or therapists. Among the children of PAGER Association members, there are several who go to the primary care doctor more than once a week on average for their severe GERD. A child with GERD may see a pediatrician, a gastroenterologist, an allergist, a pulmonologist, a clinical nutritionist, a surgeon, an Otolaryngolosts and an allergist. In addition, many of these children need special therapy that stems from untreated GERD. Some see a speech therapist, feeding therapist, swallowing therapist, physical therapist or occupational therapist as well.

GERD is particularly common in children with special needs. In conditions such as Down Syndrome, prematurity, asthma and cerebral palsy, prevalence rates are in the 50-80% range. In these children, the GERD can be more challenging than the primary diagnosis because it prevents the children from having adequate nutrition and sleep and keeps them in pain.

Pediatricians are the most appropriate caregivers to coordinate care by multiple specialists. They need to be allowed to bill for this time and to serve this function fully.

Children with GERD need access to appropriate case coordination by their own primary care doctor.

Coverage of special positioning equipment

Lifestyle changes are important in the treatment of GERD. In addition to recommending small frequent meals, effective burping and avoidance of foods that trigger GERD, doctors will often recommend the use of upright positioning most of the day and night. It is much more difficult to accomplish for children. The use of positioning isn't universally successful, but for many children it is a vital addition to medical therapy. For children who choke when laid flat, it can prevent aspiration and SIDS. Positioning therapy for adults simply means staying upright after meals and sleeping with blocks under the head of the bed. Children are unable to maintain a constant position, spend more of their day lying down and they eat so often that their stomachs are seldom empty. This means that positioning is much more difficult with children, particularly babies. The simplest way to position a child upright during sleep is to use a commercially available wedge, sling or hammock. Many parents make positioning devices at home but this is difficult to accomplish without creating a strangulation hazard. Positioning is best tried before the child learns to turn over and will likely be more upset about being moderately restrained. There are no published studies of the use of commercial devices for positioning babies with GERD. The only positioning article of home made positioning found it was too much trouble. (We consider the methodology of this study to be questionable as the children were studied for only a short time, in the hospital, and on a diet of only apple juice.)

Recommendation:
PAGER recommends coverage of prescribed positioning devices quickly and easily.

Respite Care

A typical child with GERD is more difficult to care for than a child with colic. They cry non-stop often for most of the day and night and are completely inconsolable due to excruciating pain. Babies with reflux are notoriously poor sleepers and many wake shrieking in excess of a half dozen time EACH night. Some of our parents report hallucinating due to sleep deprivation.

While simple colic will start at three weeks and stop by four months, GERD pain and crying may continue for a year or more. We have many members who live with relatives or hire a nanny so that there can be multiple caregivers on duty twenty-four hours per day.

Our primary goal is to improve the health of the child, but our more immediate goal is to provide support to the parents during what is usually the most difficult time of their lives. We worry a great deal about the potential for a parent to get so frustrated that they harm their child.

Child abuse experts agree that the most common reasons for a child to be shaken or murdered are colic-like crying, vomiting, refusing food and night waking. These risk factors for child abuse happen to be the primary symptoms of GERD. If you combine these risk factors with sleep deprivation and the need to hold the child upright most of the day to keep them from vomiting, you have a recipe for disaster.

Recommendation:
Parents of children with GERD need access to respite care.

Feeding Programs

Children who vomit or spit up frequently after meals may begin to develop aversions to food and eating. The esophagus and mouth of a child who has been vomiting quickly becomes inflamed and raw and results in pain while eating. Babies with significant GERD will often simply stop eating in an attempt to stop the pain. They may eat an ounce or so of food, but then pull away from the bottle or breast and shriek in pain. They may cry and refuse to feed for several hours despite attempts to feed them. While complete food refusal is somewhat rare, eating too little to grow is common. Untreated food aversions can rapidly develop into a serious medical situation. A daily intake of only 12 ounces is not unheard of for a child with GERD who is six months old and should be eating 2-3 times that amount. Depending on the age of the child, they may miss the critical period for learning to chew and swallow solids and may experience great difficulty learning these missed skills from a swallowing therapist. Even children who had already been exposed to solids may forget how to eat them if their reflux leads to long term refusal of solids. Children who do not get adequate practice manipulating solids are at very high risk for speech delays as learning to eat is the most important and natural practice for learning to speaking.

Food refusal can develop into a serious psychological situation if the child becomes phobic of food and distrustful of adults who are constantly trying to force him to do something that is painful – eat. Although a healthy child will eventually eat if food is offered, a child in pain won't. Children with reflux can and do starve themselves nearly to death.

Tube feeding may seem like a simple alternative to feeding therapy for food refusal or poor weight gain, but it is an option full of peril. A child who becomes dependent on tube feeding will have a great deal of difficulty leading a normal life. Tube feeding is intimidating, stressful and time consuming for caregivers. It is nearly impossible to find child care for a baby who is tube fed. A child who only needs a tube for a short period of time may be very difficult to wean back onto oral feeds. A treatment plan for tube feeding should always include an exit strategy for weaning. Feeding by tube is extraordinarily expensive. The disposable bags alone cost $5.00 each.

Feeding disorders can rapidly become intractable and resistant to simple interventions. A child with neglected GERD may eventually need to be enrolled in a feeding program. Because feeding disorders are so difficult to treat, children needing feeding therapy are often sent to distant cities for an in-patient feeding program.

Feeding programs vary drastically in the types of interventions they use to convince their little patients to eat. Some operate on a medical model and specialize in addressing lingering GERD or undiscovered allergies. Others operate on a behavioral model in which they force the child to eat through extreme coercion on the theory that there is no longer any valid or logical reason for the child to mistrust eating. Because the approaches are so diametrically opposed, parents must do careful homework to determine which program is best for their child. Given the extremely high failure rates of some programs in treating specific types of feeding problems, it makes sense to shop carefully for a program that is better suited to the child. A program that is inappropriate for the child's feeding problem can result in extreme psychological trauma and doom subsequent attempts with more appropriate feeding therapy to failure.

Recommendations:
Insurance coverage should be available for the most appropriate in-patient or out-patient program – as determined by their primary care physician in conjunction with parents and gastroenterologist - regardless of location and on an urgent basis to increase the chances for success.