

## **SIGIS: Special Interest Group for IAS Standards™ Eligible Product List Criteria (12/15/2010)**

**IMPORTANT NOTICE:** IRS rules have changed with regard to over-the-counter (OTC) medicines and drugs. Effective January 1, 2011, over-the-counter (OTC) medicines and drugs that are not prescribed by a physician will not qualify as a medical expense under IRS Code Section 213(d). As a result, OTC medicines and drugs are ineligible for purchase with an FSA or HRA debit card at a SIGIS certified merchant under the SIGIS IAS process. Such items, when accompanied by a valid prescription, may be eligible for reimbursement when adjudicated through an alternate method (e.g., paper claim). Thus, even OTC medicines and drugs accompanied by a doctor's prescription will not be included on the SIGIS List due to the incompatibility of these types of medicines and drugs with the SIGIS IAS process. Please read "Not Included as Eligible Products for IAS Approval: OTC Medicine and Drugs" below. IRS rules HAVE NOT changed for OTC products that are not medicines or drugs.

The removal of OTC medicines and drugs from the list of qualifying medical expenses will not impact SIGIS members who have locations registered under the 90% Program. 90% Program registrants can continue to include "OTC Medicines and Drugs" with other products in determining whether their store locations will qualify under the 90% Programs. Please refer to **90% Rule Program Implementation Procedures for Issuers, Issuer Processors, Acquirers and Merchants** for more information about the 90% Rule.

SIGIS has developed a list of health care over-the-counter items that are considered eligible under Internal Revenue Service (IRS) Code Section 213 rules. The list originates from a database of more than 55,000 health and beauty aid items that is continually being updated with new product introductions and discontinuations. Using the criteria in this document, SIGIS determines whether a product qualifies or does not qualify as a medical expense under IRS Code Section 213(d) and applicable IRS guidance. This list is reviewed monthly by the SIGIS List Working Group, a group of benefit plan administrators, to assure the accuracy and integrity of the list. Additions and suggested eliminations from the list are to be referred to the Working Group for monthly discussion and appropriate action.

The Eligible Product List and regular updates may be downloaded and used by all SIGIS members. Merchants certified by SIGIS or planning to be certified by SIGIS must use the Eligible Product List as a basis for identifying the items in their product database that would be eligible for submission as a SIGIS qualified healthcare product in a debit card authorization request. Benefit plan administrators may find the Eligible Product List and this List Criteria helpful in ensuring consistency between substantiation of card transactions at SIGIS merchants and other substantiation requests.

Information provided in this document is subject to change, as new information becomes available and as rules and definitions change.

### **1. Eligibility Status Definitions**

**Eligible:** Eligible products include OTC products that are for medical care and are primarily for a medical purpose. They include products (other than OTC medicines or drugs) that diagnose, alleviate or treat existing or imminent injuries, illnesses or medical conditions. As a general rule, most of these products are of short-term use but some do treat chronic medical conditions. Qualified medical expenses include those over-the-counter items compliant with federal tax rules under IRS Code Section 213(d) as outlined by the Internal Revenue Service. In these cases, the expense would not have been paid "but for" the disease or illness. An expense is not deductible as medical care if the

taxpayer would have paid the expense even in absence of a medical condition. The user does not need to provide a statement from a medical provider or indicate a diagnosis in order to receive reimbursement.

### **Not Included as Eligible Products for IIAS Approval**

**All OTC Medicines and Drugs:** OTC Medicines and drugs that diagnose, alleviate or treat existing or imminent injuries, illnesses or medical conditions may be eligible for reimbursement only if accompanied by a physician's prescription. OTC medicines and drugs that have not been prescribed by a physician are not eligible for reimbursement. As a result, OTC medicines and drugs are ineligible for purchase using an FSA or HRA debit card at a SIGIS certified IIAS merchant. Such items, when accompanied by a valid prescription, may be eligible for reimbursement when adjudicated through an alternate method (e.g., paper claim).

As noted above, these rules are new and, to date, were not accompanied by any regulatory guidance as to the definitions for "medicine" or "drugs". Existing rules state that "medicine and drugs" include only items that are "legally procured" and "generally accepted as falling within the category of medicine and drugs". Things like toiletries (e.g., toothpaste), cosmetics (e.g., face creams) and sundry items clearly are not "medicines and drugs", but antacids, allergy medicine, pain relievers, or cold medicine clearly are. Distinctions become more difficult with items that are not drugs, but may be "medicine" or "medicated". For example, is a homeopathic cough syrup made with honey a "medicine"? Is a medicated ointment a "medicine"? The SIGIS List Working Group has carefully researched each class of OTC product to determine whether or not the item is deemed a medicine or drug by the FDA and then made an appropriate determination. Thus, both homeopathic cough syrup made with honey and medicated ointment are deemed a "medicine" and have been removed from the SIGIS List

Until further guidance is released, anything that is medicated and that is ingested, injected, inhaled, inserted, or applied topically to alleviate or treat existing or imminent injuries, illnesses or medical conditions is classified as an OTC medicine or drug. However, amounts paid for non-prescription equipment, supplies, and diagnostic devices, such as crutches, bandages, and blood sugar test kits will continue to qualify as a medical expense, even without a doctor's prescription. OTC medicines and drugs will not be included in the SIGIS List.

**Dual-purpose:** Some products are considered dual-purpose. These products may have both a medical purpose and a personal hygiene, cosmetic or general health purpose. In order to be considered eligible, they must be used to treat a medical condition and cannot be used to improve or maintain general health unless prescribed by a physician to treat a specific illness, condition or injury. These products may be eligible for reimbursement, but require a letter of medical necessity from a licensed healthcare professional stating the specific diagnosis or medical condition, the specific OTC medicine recommendation to treat the condition, and documentation of the product and cost. Dual-purpose items will not be included in the SIGIS List.

**Ineligible:** Products that are used for general health, cosmetic, or personal hygiene purposes are not reimbursable. Typically, these are not referred to as medicines or drugs and are not recognized to treat a medical condition. Medical expenses that are not reimbursable under IRS Code Section 213(d) of the federal tax code are ineligible. These include food supplements, toiletries, lotions and soaps, shampoos, vitamins and most herbal supplements (note that non-prescription OTC medicine and drugs are technically ineligible, but we have included those items under the heading "All OTC

Medicine and Drugs” for purposes of this discussion). These items are also not intended to be on the SIGIS List.

The source of the list includes most **nationally-distributed, regularly-stocked items**. As such, the following types of items will generally not be included: items specially created for an individual retailer (including but not limited to private label items); a local, regional, or specialty item; bonus items (e.g. 2 oz free); BOGOS (buy one, get one), or other in-and-out types of packaging with limited availability or distribution. Although these items will not be included in the data, they may in fact be eligible. If such circumstances exist or if one feels other items meet the eligible criteria then they can be submitted through the add process on the SIGIS website. These will be reviewed by the SIGIS List Working Group and qualifying items will be added to the eligible product listing.

Because the source of the list is nationally-distributed, regularly-stocked products, private label and store branded products will generally not be available for inclusion on the standard list produced by SIGIS. It is understood that some of these private label and/or store brand items are, in fact, eligible under IRS Code Section 213(d), and therefore, can be processed through a certified SIGIS IIAS merchant. Merchants that choose to supplement their inventory of SIGIS identified eligible items with their own private label items are free to do so by following the process detailed in the Private Label Eligibility Criteria document. That document can be found at [www.sig-is.org](http://www.sig-is.org).

Alternatively, SIGIS’ vendor, Hamacher Resource Group, offers a non-SIGIS identification service to merchants, with extensive private label, store brand inventories. For more information, please contact Tom Boyer, National Account Manager, at Hamacher Resource Group (tom\_boyer@hamacher.com, 414-431-5314).

## 2. Classifications and Examples

The following are types of products that typically would be included under each designation. These are strictly guidelines and do not represent an all-inclusive listing.

### Eligible:

Category	Example	Comment
Baby Electrolytes and dehydration	Pedialyte, Enfalyte	Baby Electrolytes and dehydration
Contraceptives	Unmedicated condoms (e.g., condoms without spermicide)	
Denture Adhesives, Repair, and Cleansers	PoliGrip, Benzodent, Plate Weld, Efferdent	Denture products and maintenance covered
Diabetes Testing & Aids	Ascencia, One Touch, insulin syringes; glucose products	Include glucose tabs/gels, testing and insulin related accessories
Diagnostic Products	thermometers, blood pressure monitors, cholesterol testing	Includes devices that monitor, screen or test for the presence of disease, dysfunction of the body or for other medical conditions; drug and body fat testers are not covered (dual)
Ear Care	Unmedicated ear drops, syringes, and ear wax removal;	
Elastics/Athletic Treatments	ACE, Futuro, elastic bandages, braces, hot/cold therapy, orthopedic supports & rib belts, etc.	waist shapers, tummy supports and work related back braces are not covered (dual)

Eye Care	contact lens care	
Family Planning	pregnancy kits, ovulation kits	
First Aid Dressings & Supplies	Band Aid, 3M Nexcare, J&J First Aid, non-sport tapes, etc.	Tapes and bandages indicated as "Athletic" or "Sport" are not covered
Foot Care Treatment	Un-medicated corn & callus treatments (e.g., callus cushions), devices, therapeutic insoles	products that treat specific ailments are eligible; products for general use or comfort are not eligible (dual)
Glucosamine &/or Chondroitin	Osteo-Bi-Flex, Cosamin D, Flex-a-min Nutritional Supplements	Medical expense as long as products marketed for arthritis treatment (as opposed to mere prevention)
Hearing Aid/Medical Batteries		
Home Health Care (limited segments)	ostomy, walking aids, decubitis/pressure relief, enteral/parenteral feeding supplies, patient lifting aids, orthopedic braces/supports, splints & casts, hydrocollators, nebulizers, electrotherapy products, catheters, un-medicated wound care, wheel chairs	
Incontinence Protection & Treatment Products	Attends, Depend, GoodNites for juvenile incontinence, Prevail	skin and cleansing products not covered (dual)
Prenatal Vitamins	Stuart Prenatal, Nature's Bounty Prenatal Vitamins	
Reading glasses and maintenance accessories		accessories used to maintain corrective lenses and frames are covered; chains, etc. not covered

**OTC Medicines and Drugs (Not Included in Eligible Product List):**

It is unclear which products will fall into the category of “OTC medicine and drugs” and which products will not constitute OTC medicine and drugs but will still constitute “medical care” for purposes of reimbursement. The items listed in Table A are items that SIGIS believes will most likely constitute OTC medicine and drugs requiring a prescription for reimbursement based on prior IRS rulings, industry experts and Food and Drug Administration (FDA) classification. The items listed in Table A will not be included in the SIGIS List, although they may be reimbursed through an alternate (e.g., paper claim) substantiation process. The items listed in Table B will also be treated by SIGIS as OTC medicine and drugs requiring a prescription for reimbursement, at least until further IRS guidance is available. Items from Table B that do not constitute an OTC “medicine or drug” but that do constitute “medical care” within the meaning of IRS Code Section 213(d) will be moved to the SIGIS List once guidance is available.

<b>Table A</b>		
<b>Category</b>	<b>Example</b>	<b>Comment</b>
Acid Controllers	Pepcid AC, Zantac, Prilosec	
Acne Medications	Clearasil, OXY	
Allergy & Sinus	Alavert, Benadryl, Claritin, Sudafed	
Antibiotic Products	Bacitracin, Neosporin, triple antibiotic ointment	
Anti-Diarrheals	Imodium, Kaopectate	
Antifungal (Foot)	Lamisil, Lotrimin	
Anti-Itch & Insect Bite Remedies	Caladryl, Lanacane, Sarna, hydrocortisone	

Antiparasitic Treatments	Nix, Rid, lice treatments	
Baby Teething Pain	Baby Orajel, Anbesol Baby Oral Gel	
Cold Sore Remedies	Abreva, Herpecin, Orajel	Only medicated products are covered
Contraceptives	"morning-after pill"	
Cough, Cold & Flu	Robitussin, Theraflu, Vicks, Halls, Cepacol, Zicam, Cold-Eeze	Cold preventative products which are "proven to lessen the severity" or "reduce the duration" of colds or flu are covered. These include homeopathic, natural products, some herbals and some forms of zinc. Products that are merely dietary supplements and marketed as such, including those claiming to "support the immune system" (i.e. Airborne), are not covered. Hand sanitizers in cold not covered.
Denture Pain Relief		
Eye Care	Visine, Refresh Tears	
Feminine Antifungal and Anti-itch	Monistat, Gyne-Lotrimin, Vagisil, Soothing Care	
First Aid Burn Remedies	Dermoplast, Solarcaine	must contain an antiseptic or pain reliever, 100% aloe is not covered (dual)
Hemorrhoidal Preparations	Preparation H, Tucks	
Incontinence Protection & Treatment Products	anti-fungals, Calmoseptine	skin and cleansing products not covered (dual)
Laxatives (non-fiber)	Dulcolax, Ex-Lax, Miralax	Stimulant, saline, lubricant, etc (non-fiber)
Motion Sickness	Dramamine, Sea-band Wristband, Bonine	
Medicated Nasal Sprays, Drops & Inhalers	Afrin Spray	
Oral Remedies or Treatments	saliva substitutes, mouth sore treatments, dental repair, Salivart, Anbesol, Orajel, Dentemp	Only dry mouth that are saliva substitutes are covered (gels, sprays, etc. not mouthwash, rinses, toothpaste)
Pain Relief (includes aspirin)	Tylenol, Advil, Midol, Bayer	
Medicated Respiratory Treatments and Vapor Products	Primatene, Bronkaid, medicated Vics Vapor Rub	includes asthma medications and delivery devices like inhalers and nebulizers; vaporizers and humidifiers not covered (dual)
Skin treatments	Psoriasin, MG217, Dermarest Eczema	Medical expense as long as intended purpose is to treat existing skin conditions like eczema, psoriasis, rosecea, etc. (as opposed to mere prevention)
Sleep Aids & Sedatives	Unisom, Nytol, Sominex	
Smoking Deterrents	Nicoderm, Nicorette	
Stomach Remedies	Mylanta, Maalox, Tums	

<b>Table B</b>		
<b>Category</b>	<b>Example</b>	<b>Comment</b>
Anti-Gas	Gax-X, Phazyme	Unclear whether digestive aids with enzymes as an active ingredient are "medicine" or "drugs".
Antiseptics & wound cleansers	rubbing alcohol, peroxide, epsom salt, Betadine, Hibiclens	
Baby Rash Ointments & Creams	Desitin, Aveeno Baby	Includes petroleum jelly merchandised and marketed for baby rash
Contraceptives	female contraceptives, spermicidal foam, medicated condoms	
Digestive Aids	Lactaid, Lactase, Beano,	Unclear whether digestive aids with enzymes as an active ingredient are "medicine" or "drugs".
Ear Care	Medicated ear drops, Debrox, Similasin	
Fiber Laxatives (bulk forming)	Benefiber, Fibercon, Metamucil (powder or pills)	Covered when used to treat a medical condition for short duration; bars and drinks that are "nutritional foods" for help with regularity are not covered (dual)
Foot Care Treatment	corn & callus treatments, wart removers	products that treat specific ailments are eligible; products for general use or comfort are not eligible (dual)
Homeopathic Remedies	Boiron and Hyland products	Homeopathic medicine is a form of alternative medicine that uses very small amounts of natural substances, which in higher amounts would cause a disease. The theory behind homeopathic medicine is that "like cures like," and that a substance that causes an illness in a healthy person might cure those symptoms in someone who is ill. Such products that treat an illness or condition are eligible.
Unmedicated Nasal Sprays, Drops & Inhalers	Ocean Nasal Spray	
Unmedicated Vapor Products	Sudacare, unmedicated Vicks Vapor Rub	includes asthma medications and delivery devices like inhalers and nebulizers; vaporizers and humidifiers not covered (dual)

## Dual-purpose (Not Included in Eligible Product List):

Category	Example	Reimbursement Use
Allergy Pillows, Mattress Covers, Air Purifiers, Filters, etc.		To treat allergies diagnosed by physician.
Anti-bacterial Hand Sanitizers	Purell, Nexcare, Germ-X	Personal use component; but/for test must be established
Baby Diapers	Huggies, Pampers, Pullups	To treat juvenile incontinence or medical condition.
Baby Formulas/Nutritionals	Pediasure, Progestimil	Only specialty formulas/nutritionals are covered if medically necessary and authorized by medical practitioner
Compression Hosiery	Jobst, TED, Futuro	Including diabetic socks; excess cost over regular hose and socks
Cough, Cold & Flu dietary supplements	Airborne, Hall's Defense, Germ Defense Alka Seltzer Immunity	Products that are merely dietary supplements and marketed as such, including those claiming to "support the immune system" (i.e. Airborne), are not covered (dual). Cold preventative products which are "proven to lessen the severity" or "reduce the duration" of colds or flu are covered. These include homeopathic, natural products, some herbals and some forms of zinc.
Diabetes Nutritionals	Glucerna, Boost Glucose	To treat symptoms of diabetes when recommended by physician.
Diabetes Personal Care & Supplies	Include diabetes skin care, cough & cold, support socks and supplies	Personal care is generally not covered; must test or treat a specific symptom or condition of Diabetes
Dietary Supplements	essential fatty acids (fish oil), soy, enzymes, amino acids	Under narrow circumstances, they will be eligible if used to treat medical condition or at-risk for illness diagnosed by physician; dietary supplements marketed in pain relief, cough & cold and antacids/laxative categories do not automatically qualify as a medical expense (i.e. Azo Cranberry, Airborne, Culturelle, etc.)
Drug Testing Kits	First Check	Diagnostics of illegal activities are typically not covered
Ear plugs	Mack's, Flents	To treat medical condition (presence of middle/inner ear tubes) diagnosed by physician.
Exercise Equipment	treadmill, exercise bike	To treat medical condition diagnosed by physician & not for general health.
Face Masks - medical grade		Personal use component; but/for test must be established
Feminine Moisturizing	Replens, Repfresh	To treat vaginal dryness caused by medical condition

Feminine Protection (Pads & Liners)	Kotex, Always, Stayfree	They are ordinarily considered as being used to maintain general health and for personal care. They are dual if used for post-surgery or child birth
First Aid Burn & Scar Treatments & Skin Protectants (petroleum jelly)	aloe, Mederma, Neosporin Scar Solution, Vaseline Jelly	Most are cosmetic in nature or have general use purposes
Fluoride Treatments	Gel-Kam	To treat medical condition diagnosed by physician & not for general oral care.
Food Thickeners	Thick-It	Personal use component; but/for test must be established
Foot Insoles and Cushioning	Insoles, Heel & Arch, Dr. Scholl's Air Pillo, Odor Eaters	Treatment vs. general use or comfort; must treat specific ailment to be covered
Gloves (Rubber & Cotton)	BD	
Hair Growth Products	Rogaine	To treat symptom of medical condition diagnosed by physician.
Herbals & Botanicals	Echinacea, ginkgo biloba, garlic	Under narrow circumstances, they will be eligible if used to treat medical condition or at-risk for illness diagnosed by physician.
Home Health Care (limited segments)		Home Health Care is dual other than what is indicated in the Home Health Care eligibility section
Incontinence Personal Care	Perineal cleansers, moisturizers and general skin protectants	Personal care is generally not covered; must treat a specific symptom or condition of Incontinence
Magnifying Glasses		
Medical Nutritionals	Resource, Peptamen, Nutren	Satisfies normal nutritional needs and does not treat a specific condition
Medicated & Specialty Soaps	Basis Bar, Cetaphil Cleansing Bar	To treat skin condition diagnosed by physician.
Minerals	Calcium Carbonate, Ferrous Sulfate, etc.	Under narrow circumstances, they will be eligible if used to treat medical condition or at-risk for illness diagnosed by physician.
Nasal Strips & Snore Relief	Breathe Right	To treat sleep apnea or improper breathing diagnosed by physician.
Nutritional Foods	Ensure, Boost	To treat medical condition diagnosed by physician & not for general health.
Probiotics and Prebiotics	Culturelle, Florastor	To treat digestive condition and recommended by physician & not for general digestive health.
Skin Care - Therapeutic Hand & Body	Eucerin, Aquaphor, Amlactin	To treat or remedy a skin condition diagnosed by physician.
Sun Protection (SPF 15+)	Coppertone, Banana Boat SPF 15+	Diagnosis or history of skin cancer that is affected by sun exposure.

Therapeutic Shampoo & Scalp Treatments (Medicated)	Nizoral, Neutrogena T-Gel	To treat skin/scalp condition for short duration diagnosed by physician.
Vaporizers & Humidifiers and Accessories	Vicks, Sunbeam, Kaz	Covered if used to treat illness; not covered for normal household use
Vitamins	Vitamin A, C, D, E, multivitamin, lutein eye vitamin	Under narrow circumstances, they will be eligible if used to treat medical condition or at-risk for illness diagnosed by physician.
Weight Control Supplements	Alli, Slim Fast	To treat obesity diagnosed by physician.

### Ineligible:

Category	Example	Comment
Baby Toiletries, Baby Oil, Powder, Lotions & Creams	Johnson's Baby oil/Powder, Aveeno Baby Lotion	
Beauty Shampoos, Conditioners & Hair Treatments	Pantene, Suave, Dove, hair color	
Cosmetics	Revlon, CoverGirl	
Deodorants	Speed Stick, Degree	
Facial Cleansers	Neutrogena Deep Clean, Dove Facial Cleanser	
Feminine Cleansing Products	Massengill, Summer's Eve	
Foot Grooming	Implements, beauty & comfort, moisturizers, odor & wetness	Non-medicated
Hair Removal & Bleaches	Nair, Veet	
Hand & Body Cleansing	Dove, Dial soap	
Lip Preparations	ChapStick, lip balm	
Oral Care	Toothpaste, toothbrush, mouthwash, breath remedies	Will not qualify even if a dentist recommends a special product to treat a medical condition like gingivitis. These are primarily used to maintain general health.
Shaving & Men's Grooming	Gillette, Schick	
Skin Care	Moisturizers, hand & body, bath products	
Sport Energy Liquids, Bars, etc.	Gatorade, EAS drinks/bars	
Sugar & Salt Substitutes	Equal, Splenda	
Sun Tanning	sun tan lotion, after sun products	Sunblock SPF 15+ is dual.

### 3. Reporting items to include or delete

SIGIS members can use the Missing Product Form available at [www.sig-is.org](http://www.sig-is.org) to request items to be added or deleted. Incomplete information will not be considered.

### 4. List Availability

The list is generally available by the 9<sup>th</sup> business day of each month. Items for the List Review Working Group to be considered for addition or deletion from the SIGIS List must be submitted by the 1<sup>st</sup> business day of each month to be considered for that month's updates.

## 5. Notes:

It has been reported that some merchants are unable to include a SIGIS eligible healthcare product that may also be eligible for purchase via the Food Stamp program. Should this present a problem for any merchants, it is recommended that they should eliminate it from the SIGIS data and classify it for Food Stamp eligibility, as the consumer may submit the item for manual reimbursement from their flexible spending or health reimbursement arrangement account.

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