Texas Vendor Drug Program
Pharmacy Provider Procedure Manual

Drug Policy

May 2018

The Pharmacy Provider Procedure Manual (PPPM) is available online at txvendordrug.com/about/policy/manual.

TEXAS Health and Human Services | Medical and Social Services

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1 Drug Coverage

VDP maintains the **Texas Drug Code Index** (TDCI), or formulary, which includes program-specific drug lists for:

- Medicaid
- Children's Health Insurance Program (CHIP)
- Children with Special Health Care Needs (CSHCN) Services Program
- Healthy Texas Women (HTW) Program
- Kidney Health Care (KHC) Program

Managed care organizations are required to adhere to the Medicaid and CHIP formularies.

Texas HHSC requires drug companies to complete the Certification of Information (HHSC Form 1326) in order to request inclusion of their products on the TDCI. Drug companies must provide complete and accurate information for each product, and HHSC may return a COI without the addition of the product to the TDCI if a manufacturer fails to provide complete information.

2 Claim Requirements

2.1 Drug Format

Pharmacy claims must be submitted with the 11-digit National Drug Code (NDC) in the "Product/Service ID" field (4Ø7-D7) and '03' in the "Product/Service ID Qualifier" field (436-E1). The NDC submitted must be the actual NDC number on the package or container from which the medication was administered.

The 11-digit NDC number is composed of three segments:

- Labeler: 5-digit code assigned by the Food and Drug Administration (FDA) and identifies the drug manufacturer
- Product: 4-digit code assigned by the drug manufacturer and identifies the specific product
- Package: 2-digit code assigned by the manufacturer and identifies the package size

The correct format for pharmacy claim submission is an 11-digit number in a 5-4-2 format. Other formats (such as a 10-digit number in the 4-4-2, 5-3-2, or 5-4-1 format) must be converted prior to submittal. The NDC format can be corrected by correctly placing a leading zero (Ø) in either the labeler code, product code, or package size code to conform to the 5-4-2 format.

Refer to "Multi-ingredient Compounds" section of the System Requirements chapter of the PPPM for instructions on how to identify the NDC on a multi-ingredient compounds claim.

2.2 Drug Unit of Measure

There are three available billing units in the "Unit of Measure" field (6ØØ-28):

- Each (EA), used when the product is dispensed in discreet units
- Gram (GM), used when a product is measured by its weight
- Milliliter (ML), used when a product is measured by its liquid volume

Pharmacy staff should be aware of the correct billing units on certain medications to alleviate billing discrepancies which can lead to potential audit risks. Quantity for milliliters and grams must be divisible by package size. Some products (such as Risperdal Consta, Humira, Enbrel, Lovenox, Neupogen, Pegasys, and Procrit) may have varying units depending on the NDC number.

Refer to the NCPDP B1 Transaction Billing Request payer sheet for acceptable unit of measure values on single ingredient and multi-ingredient compound claims.

2.3 Drug Efficacy Study Implementation

Drugs that are classified with Drug Efficacy Study Implementation (DESI) values "5" or "6" are not covered.

2.4 Day Supply

The number submitted in the "Days Supply" field (4Ø5-D5) is a key field in the real-time calculation of refill too soon and performing drug use review. An incorrect value can result in inaccurate DUR alerts and can cause claims to reject for early refill.

Pharmacy staff should divide the quantity by total dosage units per day to identify the correct day supply.

Table 1 - Maximum Days Supply By Program

Program	Maximum Day Supply
Medicaid	185 days
CHIP	Up to a 90 day supply
CSHCN	185 days
KHC	34 days unless Medicare is the primary payer (KHC will pay for a 90-day supply if Medicare allows a 90-day supply

2.5 Quantity Dispensed

The "Quantity Dispensed" field (442-E7) should reflect the amount actually dispensed by the pharmacy at the point of sale. Pharmacy providers must dispense the quantity prescribed or ordered by the prescriber except as limited by the policies and procedures described in this manual. When actual quantity dispensed deviates from the prescribed quantity, the provider must bill for the amount actually dispensed. Incorrect quantities may prompt drug manufacturers to dispute the claim and cause rebate auditors to review the claim level data.

Some drugs (such as ear drops, eye drops/ointments, inhalers, and those designed to be injected) are packaged in a size that is not a whole number. When submitting a claim for a drug that is packaged in a metric decimal-sized package (e.g. 10.2; 2.5; etc.), pharmacy staff should include the decimals on the claim and not round up.

Pharmacy staff with issues resolving whole number units on the package size and submitting decimal units should contact their software vendor for further assistance.

2.6 Dispense As Written

Pharmacy staff must submit a value "1"in the "Dispense as Written (DAW) / Product Selection code" field (4Ø8-D8) when a prescribing providers wants a non-preferred brand name dispensed and hand writes the phrase "Brand Necessary," "Brand Medically Necessary," "Brand Name Necessary," or "Brand Name Medically Necessary" across the face of the prescription. The value of “1” will reimburse at the normal calculated cost, including comparison to the submitted "Usual and Customary Charge" and "Gross Amount Due" fields. The value of “1” is not needed

if the brand drug prescribed has preferred status on the Texas Medicaid Preferred Drug List.

If an e-prescription is received by a pharmacy with “dispense as written” indicated but without the free text message ("Brand Medically Necessary") or additional note, pharmacy staff must contact the prescriber for a new prescription. Once the pharmacy receives the e-prescription with both of these data elements, the claim may be submitted.

Failure of the pharmacy to produce electronic records that indicate the proper DAW and “Brand Medically Necessary” in the free text message for the prescription will result in the claim subject to recoupment. All non-electronic “Brand Medically Prescriptions” (for controlled and non-controlled substances), must continue to comply with current policy and Texas State Board of Pharmacy rules.

2.7 Prescription Splitting

The same drug in the same strength should be dispensed no more than once per month, per person. An exception to this is only for medications that may be considered too unstable to be dispensed as a one-month supply.

3 Claim Limitations

This section identifies claim limitations for claims processed by VDP (for traditional Medicaid, CSHCN, HTW, and KHC programs) or by the managed care organization. If no guidance is given for MCO processing, pharmacy staff should contact the MCO for plan-specific limitations.

3.1 Prescription Limits

3.1.1 Medicaid

People enrolled in Medicaid are limited to three (3) prescriptions per month with the exception of:

- Children under the age of 21
- People enrolled in managed care
- People enrolled in eligibility waiver programs

Drugs and products that are not counted as part of the three-prescription limit include:

- Family planning drugs
- Diabetic supplies
- Smoking cessation products
- Home health supplies
- Mosquito repellent

3.1.1.1 Vendor Drug Program

Payment for up to a six-month supply may be allowed for adults with monthly prescription limitations dependent on the drug prescribed. Quantities should not exceed a one-month (34-day) supply for people with an unlimited number of prescriptions per month.

3.1.2 CHIP

People enrolled in CHIP have unlimited prescriptions.

3.1.3 CSHCN Services Program

People enrolled in the CSHCN Services Program have unlimited prescriptions. The CSHCN Program is limited by the availability of appropriated funds. Upon notification to eligible people and providers, services may be adjusted periodically depending upon current availability of funds. If a person is dually enrolled in Medicaid and CSHCN, the Medicaid benefit should be used first, including those people limited to 3 prescriptions per month.

3.1.4 KHC Program

People enrolled in KHC are limited to four (4) prescriptions per month. The number of prescriptions per month that the program will cover per person is based on available KHC funds, and the number of prescriptions covered may change depending on budget limitations. Notification will be sent 30 days in advance if the prescription number limitation changes.

3.2 Refill Limitations

Prescription refills are allowed based on the drug schedule outlined in Table 2.

Table 2 - Refill Limitations

DEA Schedule	Refill Limitations
No schedule	Original prescription plus 11 refills within 365 days from the date the original prescription was written.
Schedule 2	No refills
Schedule 3, 4, 5	Original prescription plus 5 refills within 185 days from the date the original prescription was written.

3.3 Refill Authorization

Refills may only be submitted when requested by the individual. Providers must not bill Medicaid unless the person has requested the refill – this includes pharmacies that use automated refill systems/programs.

3.4 Partial Fills

No partial fill processing is allowed.

3.5 Refill Utilization

A refill is considered too soon, or early, if the person has not used at least 75% of the previous fill of the medication.

3.5.1 Vendor Drug Program & CSHCN

A refill for certain controlled substances, as well as tramadol, is considered too soon if the person has not used at least 90% of the previous fill of the medication. Some drugs, such as attention deficit hyperactivity disorder drugs and certain seizure medications, are excluded from this requirement. To identify drugs that require 90% utilization please visit the online Formulary Search and select the "90% Utilization" filter. The returned results will include only those drugs that meet this requirement.

Claims that have not met the utilization threshold will reject with error code 79. Note the previous fill may have been from a different pharmacy provider.

3.5.2 Refill Too Soon Overrides

3.5.2.1 Vendor Drug Program

If an early refill of a drug is requested, pharmacy staff should contact VDP Pharmacy Benefits Access Help Desk to request an override. Justifications for an override include, but are not limited to, 1) a verifiable dosage increase or 2) anticipated prolonged absences from the state. Prescribing providers may be asked to verify the reason for the early refill by the pharmacy or VDP staff.

3.5.2.2 Managed care

Pharmacy staff should contact the MCO for specific requirements and processes related to dispensing early refills.

3.6 Dollar Limits

3.6.1 Vendor Drug Program

Claims are limited to $9,999.99. For claims $10,000.00 and greater, pharmacy staff should contact Pharmacy Benefits Access Help Desk.

4 Drug-Specific Requirements

This section will identify certain drug requirements for claims processed by the Vendor Drug Program (for traditional Medicaid, CSHCN, HTW, and KHC programs) or by the managed care organization. If no guidance is given for MCO processing then pharmacy staff should contact the MCO for any claim submission requirements.

4.1 Anorexic Products

4.1.1 Vendor Drug Program

Prior approval is required for ages 21 years and over. Weight management diagnoses will be denied. Claims will reject with NCPDP error code 75 and include the message “Prior Authorization not on file. Contact Pharmacy Benefits Access” in “Additional Message Information” field (526-FQ). VDP clinician staff will make the determination for coverage, and no form is required.

4.2 Anti-Fungal Products

4.2.1 Vendor Drug Program

People eligible for Medicaid will be limited to 180 day supply per calendar year. Claims will reject with error code 76 and the message "Days Supply Limited per Year by Program. Contact Pharmacy Benefits Access" in the “Additional Message Information” field (526-FQ). VDP clinician staff will make the determination for coverage, and no form is required.

4.3 Biosynthetic Growth Hormone Products

4.3.1 Vendor Drug Program

Prior approval and documentation of appropriate diagnosis is required. Prior authorization criteria is available for review at txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa. Refer to "Pharmacy Prior Authorization" section of the Contact Information chapter of the PPPM to contact the Texas Prior Authorization Call Center.

4.3.2 CSHCN Services Program

Prior approval and documentation of appropriate diagnosis is required. Download the **Growth Hormone Products Authorization Request** (HHSC Form 1312) fromtxvendordrug.com/formulary/prior-authorization/cshcn. Forms should be submitted to the CSHCN Services Program as instructed on the form.

4.4 Blood Factor Products

4.4.1 Vendor Drug Program

Pharmacy staff must submit one compound claim when the drugs are of the same active ingredient, from the same drug manufacturer, and are the same drug formulation, intended for use together with each dose. The multi-ingredient compound claim should contain one line item per NDC. Refer to the System Requirements chapter of the PPPM for claim submission requirements for multi-ingredient compounds.

4.4.2 CSHCN Services Program

Products are covered and used in the treatment of hemophilia; however, claims are processed and paid by the Texas Medicaid Healthcare Partnership (TMHP).

4.5 Compound-only Products

4.5.1 Vendor Drug Program

Certain drugs are only covered when part of a multi-ingredient compound claim. Please refer to the online formulary search to identify drugs that have this limitation. Users should refer to the drug details page of the search and find the segment that reads "Compound-only Use for <program>." Refer to the System Requirements chapter of the PPPM for instruction on how to receive payment for non-covered products that are part of a multi-ingredient compound claim.

4.6 Cough and Cold Products

Cough and cold combination products for children less than 2 years of age are not covered. This excludes single entity antihistamines. Other uses of cough and cold products for children less than 6 years of age are subject to clinical prior authorization. Products containing acetaminophen, ibuprofen, or narcotics for children less than 6 years of age will be are not covered. Products will require prior authorization if the product is not indicated for the person's age. Products containing a narcotic will require prior authorization if a child is between 6 and 12 years of age.

4.7 Cystic Fibrosis Treatment Products

4.7.1 Vendor Drug Program

Claims for Orkambi require clinical prior authorization. The Medicaid criteria (Orkambi and Kalydeco) is available at txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa.

4.7.2 Managed care

The Orkambi clinical prior authorization is required. The Kalydeco clinical prior authorization is optional.

4.7.3 CSHCN Services Program

Claims for Cayston, Kalydeco, Pulmozyme, and inhaled tobramycin require prior authorization with documentation of appropriate diagnosis required. Download the **Cystic Fibrosis Treatment Products Authorization Request** (HHSC Form 1143) fromtxvendordrug.com/formulary/prior-authorization/cshcn. Forms should be submitted to the CSHCN Services Program as instructed on the form.

Pharmacy staff can perform an eligibility verification (E1) transaction to find a person's most current period of approval for Tobramycin. Refer to the System Requirements chapter of the PPPM for information about claim transactions. Refer to the "Field Responses for an Accepted Eligibility Verification" in the NCPDP E1 Transaction Accepted Response payer sheet for further explanation about the response.

4.8 Enzyme Replacement Therapy Products

4.8.1 Vendor Drug Program

Prior authorization is required for the enzyme replacement therapy products Adagen, Aldurazyme, Ceprotin, Cerezyme, Elaprase, Elelyso, Fabrazyne, Lumizyme, Myozyme, Naglazyme, and VPRIV. Download the **Enzyme Statement of Medical Necessity** (HHSC Form 1328) from txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa. Forms should be submitted to VDP as instructed on the form. Approvals are valid for a maximum of one calendar year.

4.8.2 CSHCN Services Program

Claims will reject with NCPDP error code 75 and the message "Prior Authorization not on file. Contact Pharmacy Benefits Access" in "Additional Message Information" field (526-FQ).

4.9 Erectile Dysfunction Products

Erectile dysfunction drugs are not a covered benefit of any program.

4.10 Family Planning Products

4.10.1 Vendor Drug Program

Certain family planning products are covered, and do not count towards a person's three prescription-per-month limit. Users should select the "Family Planning" filter on the online formulary search to identify these drugs.

4.10.2 CSHCN Services Program

The prescribing physician must compose a letter of medical necessity (LMN) on office stationery. Pharmacy staff must submit the LMN by fax to the CSHCN Service Program.

4.10.3 CHIP

Birth control is only covered for certain diagnoses. Pharmacy staff should contact the MCO for any claim submission requirements.

4.11 Human Immunodeficiency Virus Products

4.11.1 CSHCN Services Program

People are allowed 60 days of drug coverage with prior authorization. Pharmacy staff should contact CSHCN to receive prior authorization. The 60-day timeframe provides coverage while the person enrolls and receives approval or denial from the Texas HIV Medications Program. If the person is not eligible for the HIV program, the medications may be an ongoing benefit through the CSHCN Services Program as long as the person remains eligible. Information on the Texas HIV Medication Program is available at dshs.texas.gov/hivstd/meds/ or by calling 1-800-255-1090.

4.12 Insulin and Insulin Syringes

4.12.1 Vendor Drug Program

Insulin syringes are a benefit only when the syringes are for insulin use. If insulin syringes are prescribed for other injectable drugs then they should be billed as a Medical benefit through the Texas Medicaid & Healthcare Partnership (TMHP). Only the insulin counts toward the person's prescription-per-month limit. Pharmacy claims for insulin may be submitted with a day supply based on stability rather than the actual dose.

4.12.2 KHC Program

Prescriptions for syringes and home health supplies will count toward the KHC prescription limit.

4.13 Influenza Vaccine

Influenza vaccine is a benefit of Texas Medicaid for high-risk individuals who are not covered by THSteps or Texas Vaccines for Children (TVFC) Program or when the vaccine is not declared available through the TVFC.

4.13.1 Vendor Drug Program

The influenza vaccine is not payable as a pharmacy benefit.

4.13.2 Managed care

MCOs are not required to offer an influenza vaccine as a pharmacy benefit. Should an MCO choose to offer the vaccine benefit, the MCO may allow its network pharmacies to administer the vaccine and only to Medicaid adults (age 18 and older) and CHIP Perinate mothers.

4.14 Kidney Transplant Drugs

4.14.1 KHC Program

Kidney transplant drug require prior authorization. Claims will reject with error code 75 and message “Call KHC Program (800) 222-3986” in “Additional Message Information” field (526-FQ).

4.15 Long-Acting Reversible Contraception Products

Providers can prescribe and obtain long-acting reversible contraception (LARC) products that are on the Medicaid and HTW formularies from certain specialty pharmacies for women enrolled in Medicaid (traditional and managed care) or the HTW Program. Products currently available through the pharmacy benefit are shown in Table 3.

LARC products are only available through a limited number of specialty pharmacies that work with LARC manufacturers. Providers who prescribe and obtain LARC products through the specialty pharmacies listed will be able to return unused and unopened LARC products to the manufacturer's third-party processor. For more

information on the buy-back program visit txvendordrug.com/formulary/long-acting-reversible-contraception-products

Table 3 - Long-Acting Reversible Contraception Products

Drug Name	National Drug Code (NDC)
Mirena	50419042101
Mirena	50419042301
Nexplanon	00052433001
Paragard	51285020401
Skyla	50419042201
Kyleena	50419042401

Providers may also continue to obtain LARC products through the existing buy-and-bill process.

4.16 Makena

4.16.1 Vendor Drug Program

Makena (hydroxyprogesterone caproate injection) requires a clinical prior authorization. Download the **Makena Clinical Prior Authorization Request Form** and submit to the Texas Prior Authorization Call Center. Refer to the "Pharmacy Prior Authorization" section of the Contact Information chapter of the PPPM for form submission requirements.

4.16.2 Managed care

Clinical prior authorization may be required. Provider and pharmacy staff should contact MCO for requirements and forms. Refer to the "Managed Care" section of the Contact Information chapter of the PPPM for form submission requirements.

4.17 Migraine Medications

4.17.1 Vendor Drug Program

Medications are limited to specific quantities per calendar month for each drug. Claims that meet the limitation will reject with error code 76 and the message

"Exceeds Max Product Quantity/Month – MI" in "Additional Message Information" field (526-FQ).

4.18 Over the Counter Drugs

4.18.1 Vendor Drug Program

Medicaid, CSHCN, and KHC cover some over-the-counter (OTC) drugs. OTC drugs are not covered for people residing in a nursing facility.

4.18.2 CHIP

Insulin, diabetic supplies, and mosquito repellant are the only covered OTC items.

4.19 Peritoneal Treatment Products

4.19.1 KHC Program

Peritoneal product claims will reject with NCPDP error code 75 and the message "Prior Authorization not on file, call the Pharmacy Benefit Access" in "Additional Message Information" field (526-FQ).

4.20 Premium Preferred Generic Drugs

4.20.1 Vendor Drug Program

Pharmacies are reimbursed an additional $0.50 incentive fee for dispensing premium preferred generic (PPG) drugs to Medicaid-eligible people. The PPG amount is returned in the "Incentive Amount Paid" field (521-FL) of the paid claim response. The incentive does not apply to $0.00 total payment amount claims. Refer to the Drug Pricing and Reimbursement chapter of the PPPM to learn more about VDP reimbursement calculation.

4.21 Pediculosis Treatment Products

4.21.1 Vendor Drug Program

Doctors can write one prescription per person in an amount that would cover the whole family if a person is diagnosed with lice or scabies.

4.22 Prenatal Vitamins

4.22.1 Vendor Drug Program

Vitamins are limited to females under the age of 50, and claims will reject for improper age or gender:

- Error code 6Ø ("Product Not Covered for Patient Age – PN")
- Error code 61 ("Product Not Covered for Patient Gender – PN")

4.23 Specialty Drugs

4.23.1 Managed care

HHSC provides a quarterly specialty drug list (SDL) to MCOs that identifies those specialty drugs that may be exclusively provided through the MCO's specialty pharmacy network.

4.23.2 Vendor Drug Program

Specialty drugs on the SDL may be covered as either an outpatient pharmacy benefit, a medical/physician benefit, or) both. For brand/generic availability, diagnosis restrictions, and billing information, for products that are covered as a medical/physician service, refer to the Texas Medicaid Provider Procedure Manual. Refer to the "Texas Medicaid and Healthcare Partnership" section of the Contact Information chapter of the PPPM for form submission requirements.

4.24 Stadol

4.24.1 Vendor Drug Program

Stadol is limited to 10 millimeters per calendar month (or 4 bottles). Claims that exceed this limitation will reject with NCPDP error code 76 ("Plan Limitations Exceeded") and the message "Exceeds Max Product Quantity/Month – ST" in "Additional Message Information" field (526-FQ).

4.25 Synagis

Synagis is used to help prevent serious lung disease caused by respiratory syncytial virus (RSV) in infants born prematurely and certain other children at high risk for

severe lung disease from RSV. More information, including seasonal requirements, is available at txvendordrug.com/formulary/prior-authorization/synagis.

4.25.1 Season

The start and end of RSV season in Texas is based on a person's county of residence. RSV appears earlier in some counties and remains active later in other counties. HHSC uses RSV statistics from prior years plus regular virology reports to determine the season's start and end dates for each region, and reserves the right to extend or end a season after subsequent review of RSV levels in each region. MCO medical directors are allowed to end the RSV season for their MCO, by service area, if they demonstrate to HHSC that the local virology has dropped below 10% positivity for two consecutive weeks.

4.25.2 Prior Authorization

4.25.2.1 Managed care

Providers and pharmacy staff should contact the MCO for prior authorization requirements and forms. Refer to the "Managed Care" section of the Contact Information chapter of the PPPM for contact instruction.

4.25.2.2 Vendor Drug Program

Prior to start of the RSV season download the **Medicaid Synagis Authorization Request** (HHSC Form 1033) from txvendordrug.com/formulary/prior-authorization/synagis/. Forms should be submitted to the Texas Prior Authorization Call Center as instructed on the form. Refer to the "Pharmacy Prior Authorization" section of the Contact Information chapter of the PPPM for form submission requirements.

4.25.2.3 CSHCN Services Program

Prior to start of the RSV season download the **CSHCN Synagis Authorization Request** (HHSC Form 1055) from txvendordrug.com/formulary/prior-authorization/synagis/. Forms should be submitted to the CSHCN Services Program as instructed on the form. Refer to the "Pharmacy Prior Authorization" section of the Contact Information chapter of the PPPM for form submission requirements.

4.26 Tramadol with Codeine

4.26.1 Vendor Drug Program

Products containing tramadol and codeine are not available for children younger than 12. Medicaid claims will deny with NCPDP error code 60 ("Product/Service Not Covered For Patient Age") and include the message "Not Covered For Under Years Of Age" in the "Additional Message Information" field (526-FQ). These products are not allowed in a multi-ingredient compound claim for this population.

4.27 Xenical

4.27.1 Vendor Drug Program

Xenical is available only for the treatment of hyperlipidemia, and will not be approved for concurrent use with other cholesterol-lowering agents. VDP clinician staff will make the determination for coverage. Download the **Xenical Authorization Request** (HHSC Form 1331) from txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa. Forms should be submitted to VDP as instructed on the form.

5 Drug Shortage

HHSC encourages pharmacy staff to notify VDP about potential drug shortages that impact prescribing choice and pharmacy claim processing.

Download the **Drug Shortage Notification** (HHSC Form 1315) from the "Downloads" page at txvendordrug.com/resources/downloads. The notification may be used by pharmacy staff, managed care organization staff, or pharmacy stakeholders to report significant drug shortages that affect multiple pharmacies and distributors, and will have continuing adverse impact on people enrolled in Medicaid if not resolved in a timely manner.

The process ensures notification of alternatives to the shorted drug, timeline of the shortage, and the drug's availability for use. Requestors should provide as much of the following information on the form.

1. Reason for reporting the shortage

2. Extent of shortage, if known
3. Estimated Length of Issue Timeline
4. Product Status Change
5. Change in status that requires new application, NDC change
6. Alternative
7. Published Notices
    a. (E.g. FDA, American Society of Health-System Pharmacists, etc.)

Referrals should recommend an alternative with supply chain in mind so extra demand will not cause another shortage.