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Tablet Splitting for Cost Containment

Introduction

Pharmaceutical manufacturers provide many medications in a variety of dosage strengths to facilitate titration of the appropriate dose to each patient. These different strengths of the same medication often have little or no price differential. For example, the 20 mg tablet and the 40 mg tablet of a particular drug may have the same price. By prescribing one-half tablet of the 40 mg strength instead of one full tablet of the 20 mg strength, the cost of the medication can be approximately halved.

In cases where patients are unable to afford their medication, physicians and pharmacists have sometimes worked together to enable the patient to obtain a higher dosage than is needed with a plan to cut the dosage forms in half. This approach can result in substantial cost savings for the patient.

However, this cost saving strategy is not always possible or appropriate. There are pitfalls with this approach that must be anticipated and avoided. Both the patient and the medication must be carefully chosen for the strategy to succeed.

The patient must be able to understand and implement the tablet splitting approach. Expecting the patient to be able to split tablets is unrealistic if the patient has:

- Cognitive impairment that limits the ability of the patient to understand and remember instructions for tablet splitting
- Arthritis or other impairment of manual dexterity
- Parkinson’s disease or other tremors
- Visual impairment

Tablet splitting is an extra step in the process of medication administration. To overcome this additional barrier, patients must be motivated to take their medication. The motivation and desire of the patient to take the medication must be great enough to overcome the need to do the additional work of tablet splitting.

The medication must also be carefully chosen. Medications that are enteric coated or have sustained release formulations are generally not suitable for splitting prior to administration. Capsules can also not be split since the capsule contents cannot be precisely divided or properly contained after the split. Scored tablets are generally easier to split.

Another consideration is the stability of the medication when exposed to air. Medication stability is generally studied with intact tablets. The effect of exposing cut tablets to the environment, as when tablets are cut in half before the dosage is taken, is often unknown. Many medications decompose rapidly when exposed to air and/or moisture.

A final consideration is the therapeutic or toxic window for the medication. With some medications, dosages must be carefully titrated and maintained to prevent either adverse effects or therapeutic failure. Because splitting of tablets produces high variability of tablet fragment sizes, the practice would be inappropriate with narrow therapeutic index medications.

Physicians and pharmacists are aware of the limitations and risks associated with tablet splitting. This approach is generally pursued with carefully selected patients, weighing the risks of tablet splitting against the likelihood that the patient will be unable to afford therapy at all without this approach.

Tablet Splitting and Health Policy

In recent years, health care payers have begun to consider tablet splitting as a strategy to save money for their health plans or programs. These plans deny payment for lower strengths of certain medications, requiring the patient to obtain the higher strength and split the tablets. The patients most affected by these policies are children and the elderly, who often need the lower dosage.

Rather than encouraging careful patient selection for this cost containment strategy, health plans reverse the process. All patients are automatically included. Access to the lower strength dosage forms is either denied or requires completing a prior authorization where the physician must demonstrate that the patient is unable to comply with the tablet splitting requirement. These policies have been implemented without research to evaluate their impact on health outcomes of the populations served. As health policy, tablet splitting is especially unsuitable for Medicaid populations, where a high proportion is elderly, disabled, or functionally impaired.

Research on Tablet Splitting

Teng and colleagues conducted a study of 11 commonly split tablets and evaluated the resulting half-tablets for content uniformity.[1] Eight of the 11 tablets, when split, failed to produce half-tablets that met a liberal adaptation of the content uniformity test for tablets from the United States Pharmacopeia. These half-tablets did not contain between 85% and 115% of the intended dosage. Notably, scoring of the tablet did not predict whether the tablet would pass or fail this test.

McDevitt and colleagues evaluated the accuracy of tablet splitting by healthy volunteers.[2] Ninety-four volunteers each split 10 tablets of 25 mg of hydrochlorothiazide. The split tablets were weighed with an analytical balance to determine accuracy of splitting. Of the split tablet portions, 41.3% deviated by more than 10% from ideal weight, and 12.4% of the portions deviated by more than 20%. After this experience, 77.2% of the subjects stated a willingness to pay more for a standard tablet of the lower strength.

Rosenberg and colleagues evaluated variability of tablet fragments dispensed by a pharmacy.[3] In this study, 30 of 560 tablet fragments (5.4%) deviated by more than 15% from the ideal weight. This level of accuracy was higher than reported by McDevitt with healthy volunteers, but still represents a significant variation.

What Can Go Wrong with Tablet Splitting?

It is important to recognize the risks involved in tablet splitting. In each step of the medication use process, the potential exists for miscommunication, errors, and adverse outcomes.

- On the prescription order, a prescription written for 1/2 tablet might be misread as 1-2 tablets.

- If the original prescription was for a whole tablet and the physician told the patient to take one tablet, the patient might follow the doctor's original advice instead of the revised plan with splitting the tablets.
- The patient may assume his or her prescription tablets have already been split (when they have not been) and take whole tablets instead of splitting them.
- If the tablets were split before dispensing, the patient may split them again without realizing or remembering that they have been split already.
- Confusion can result when the patient gets the medication refilled and the pharmacy splits the tablets when they have not previously done so, or vice versa.
- Patients may forget that they need to split a particular medicine, or get confused and split the wrong medicine.
- Patients may split the tablets unevenly and experience adverse effects from an excessively high dosage or exacerbation of the disease from a dosage that is too low.
- When the unused portion of split tablets are returned to the prescription bottle, tablet fragments can continue to crumble or split off before they are eventually used.
- Patients may get tired of splitting tablets and just stop taking the medication.

Tablet Splitting—Considerations for the Pharmacist

When tablet splitting is under consideration as a strategy for cost containment by a health plan or program, it is essential to consider what role (if any) is expected of the pharmacist and the dispensing pharmacy. If the pharmacist is to have any involvement in tablet splitting, these are the questions that must be considered from the pharmacist's perspective:

- Is tablet splitting legal?
- Will the pharmacist's malpractice insurance provide coverage for the practice?
- Is tablet splitting consistent with good patient care?
- If the pharmacist actually splits the tablets, how will the compounding fee be paid?

Tablet splitting is considered compounding by the pharmacist. It involves customization of a prescription that goes beyond providing a commercially prepared product to the patient. It also involves extra time and effort beyond that required for a typical prescription.

Pharmacists can legally compound prescriptions, but certain limitations exist under Section 503A of the FDA Modernization Act of 1997. There is no problem if the pharmacist is splitting the lowest commercially available strength of a tablet to create a customized dose for a patient who needs less of the drug. However, if the pharmacist is splitting tablets to reproduce a dosage that is commercially available, this action could be interpreted as a violation of the federal statute which says: "A drug product may be compounded … if the licensed pharmacist … (D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." (emphasis added)[4]

The question of whether malpractice insurance provides coverage for tablet splitting is related to the first question.

Baker says: "Most policies contain an exclusion similar to this: 'This policy does not apply to … damages caused by your willful violation of a regulation or statute pertaining to the practice of pharmacy … committed by you or with your knowledge or consent.'"

The pharmacist must also consider whether tablet splitting is consistent with good patient care. Is the patient a suitable candidate for tablet splitting? Does the patient understand the risks and is the patient willing to assume those risks? Is the medication suitable for splitting? The professional judgment of the pharmacist applies in the decision to split tablets for the patient or to dispense tablets that will need to be split by the patient.

Finally, what is the mechanism to compensate the pharmacist for compounding the prescription for the patient? Does the health plan provide a compounding fee as part of the tablet splitting strategy? If the patient is expected to split the tablets, will the health plan pay for a tablet cutter for the patient?

Conclusion

The American Society of Consultant Pharmacists has issued a position statement strongly opposing policies to deny payment for lower strengths of tablet dosage forms, or otherwise mandate splitting of tablets by patients.[5] In an editorial in Pharmacy Today, Daniel A. Hussar, Remington Professor of Pharmacy at the Philadelphia College of Pharmacy, stated: “Tablet splitting for economic reasons is bad patient care and bad pharmacy practice.”[6]

References

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